UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

OKLAHOMA POLICE PENSION FUND AND RETIREMENT SYSTEM, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. TELIGENT, INC. and JASON GRENFELL-GARDNER, Defendants.	Case No. 1:19-cv-03354-VM

PLAINTIFF'S SECOND AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS

Lead Plaintiff Oklahoma Police Pension Fund and Retirement System ("Oklahoma Police" or "Plaintiff"), by and through its attorneys, and on behalf of all others similarly situated, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief are based on, among other things, its counsel's investigation, which includes, without limitation: (a) a review and analysis of regulatory filings made by Defendant Teligent, Inc. ("Teligent" or the "Company") with the U.S. Securities and Exchange Commission ("SEC"); (b) a review and analysis of the U.S. Food and Drug Administration's ("FDA") regulatory findings and observations regarding the extent of Teligent's compliance with relevant laws and regulations; (c) a review and analysis of press releases and media reports issued and disseminated by the Company; (d) a review of other publicly available information concerning the Company; and (e) investigative interviews with former personnel with first-hand knowledge of the Company's operations.

I. SUMMARY OF CLAIMS

1. This is a securities fraud class action brought to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act") on behalf of all persons or entities that purchased or otherwise acquired Teligent common stock between March 7, 2017 and November 6, 2017, inclusive (the "Class Period"), and who were damaged thereby. The Defendants here are Teligent, a small pharmaceutical company, and Jason Grenfell-Gardner ("Grenfell-Gardner"), the Company's Chief Executive Officer ("CEO"), who sought to radically accelerate the pipeline of core generic treatments the Teligent submitted to the FDA for approval ("ANDAs"), and to simultaneously expand Teligent's business into new product lines.

2. Defendants made a series of materially false and misleading statements during the Class Period that touted Teligent's ability to develop and submit ANDAs in compliance with

stringent FDA regulations and to secure their approval from the FDA, going so far as to falsely deny receiving any recent 483 Letters from the FDA, which list serious compliance failures. In truth, as Defendants knew and concealed, Teligent had received a 483 Letter from the FDA in September 2016, just months before the Class Period started, listing multiple systemic compliance failures. For example, a follow-up letter from the FDA in February 2017, addressed to Grenfell-Gardner, stated that the 483 observations, **"*raise[d] concerns about the validity and integrity of the studies conducted at [Teligent's] study site*."** [Emphasis added]. These longstanding and substantial failures undermined Teligent's pipeline of new treatments, and therefore, its ability to generate revenue and grow. Moreover, these problems were so deeply ingrained in Teligent's slipshod practices that it received two subsequent 483 Letters: before the end of the Class Period in October 2017, and after the Class Period ended in May 2019. The subsequent 483 Letters showed substantially similar compliance failures by Teligent as the September 2016 483 Letter, and the compliance failures they showed also occurred during and before the Class Period. Each of those 483 Letters was at least partially in response to poor ANDA submissions that Teligent had made with the FDA.

3. Thus, though Defendants' acceleration and transformation plan did initially allow Grenfell-Gardner to tout an increased number of ANDA submissions in the run-up to the Class Period, those submissions were illusory. Teligent achieved that increase only by cutting corners and systematically failing to comply with demanding FDA regulations. As the FDA observed, Teligent: failed to have or follow required standard operating procedures ("SOPs") and controls, failed to investigate required tests that generated out-of-specification ("OOS") results, failed to validate the methods with which it undertook required tests, and failed to store required records

and data. In sum, these failures undermined the integrity of the data and products that Teligent was submitting to the FDA for approval.

4. Teligent's corner-cutting and compliance failures were a direct extension of Grenfell-Gardner's attempt to rapidly accelerate the Company's ANDA submissions, while simultaneously expanding its business, at a massive expense, prior to and during the Class Period. Fulfilling all of the time consuming regulatory requirements designed to ensure product safety and properly grow an ANDA pipeline would have required enormous resources, which Teligent, a company of less than 200 people, did not have and which Grenfell-Gardner diluted among new business lines in any event. So, Teligent simply failed to follow FDA regulations at virtually every phase of the generic development process. Also contributing to these failures, as Teligent eventually admitted to the FDA, the Company had badly understaffed the Quality Control department that was supposed to prevent them.

5. The same faulty practices that fueled Teligent's illusory increase in ANDA submissions before the Class Period also caused its ANDA submissions to slow to an almost complete halt by the start of the Class Period. For, by the time the Class Period began in March 2017, Teligent had to commit substantial resources to respond to the compliance failures observed in the September 2016 483 Letter. Teligent was not able to make such a commitment without diverting resources from its attempts to submit new ANDAs, as it had to concentrate on building up the adequate staff and control infrastructure that it failed to put in place years earlier.

6. Thus, Teligent's compliance failures and response thereto resulted in its new ANDA submissions grinding to a virtual halt during and after the Class Period. Compared to the 11 ANDAs it submitted in 2014, 15 ANDAs submitted in 2015, and 12 ANDAs submitted in 2016: Teligent managed only 4 ANDA submissions in 2017. That brought Teligent all the way back to

its low submission levels from before 2014, before Grenfell-Gardner implemented his illusory "transformation" plan. Burdened by its continuing compliance failures, as the October 2017 and May 2019 483 Letters illustrate, Teligent has remained at those low submission levels following the Class Period: it submitted only 3 ANDAs in 2018, and has not announced a single ANDA submission for 2019 as of the date of this filing (December 9, 2019). Teligent has also had to redo tests and studies in a more robust and time-consuming manner for multiple ANDAs it had already filed with the FDA in an attempt to salvage their chance of winning approval, which further delayed their progress as well.

7. This sharply diminishing pipeline occurred despite massive increases in research and development ("R&D") costs and other expenses that Teligent took on as part of the "transformation" plan beginning in 2014. The combination of limited revenue from the diminished pipeline and substantial costs has resulted in Teligent suffering significant net losses in 2017, as well as 2018 and 2019.

8. Significantly, Grenfell-Gardner knew that the FDA had observed multiple compliance failures by Teligent well before the Class Period started. For example, the FDA inspected Teligent in September 2016, about six months before the Class Period. Following that inspection, the FDA sent a 483 Letter and other official documents discussing Teligent's compliance failures between September 2016 and February 2017 that were addressed to Grenfell-Gardner and/or noted that all FDA correspondence was to be addressed to him. For the same reasons, he also knew of the two subsequent 483 Letters. Of course, Grenfell-Gardner did not need the FDA to tell him that Teligent was systematically failing to comply with required regulations. He was the CEO of a small company, whose office was in the same complex as Teligent's plant where the violations occurred; his direct-reports included the Chief Scientific

Officer, Plant Manager, and Senior Vice President of Quality Control; and Teligent tracked out-of-specification results and non-conformance reports that evidenced the compliance failures. However, Grenfell-Gardner has never disclosed any of the 483 Letters.

9. Instead, during the Class Period, Grenfell-Gardner repeatedly touted Teligent's purportedly strong record of compliance with FDA regulations. As an example, he claimed that "***there have been no 483 observations at [Teligent's] site.***" [Emphasis added]. Similarly, he assured investors that "***our cooperation with the FDA has been incredibly fruitful and straightforward***." [Emphasis added]. He also used Teligent's purported compliance prowess to justify the Company's exorbitant R&D costs, asserting that R&D is "***the best investment that we can make because the FDA is approving the drugs that we submit***" and so driving the Company's growth. [Emphasis added].

10. Those statements were materially false and misleading because, among other things, at the time they were made:

(a) As described in the FDA's correspondence with Teligent in September 2016, October 2017, and May 2019, as well as by CW1, before and during the Class Period, Teligent had a widespread failure to implement required procedures and controls, exacerbated by a badly understaffed Quality Control department. This resulted in Teligent systematically failing to comply with FDA regulations, which undermined the integrity of the data Teligent submitted to the FDA in support of its ANDAs. Indeed, Teligent not only had to redo tests and studies for the faulty ANDAs it had submitted, so that they had a chance of receiving approval, but it had to implement a host of new procedures and controls across its laboratory and related infrastructure – in response to compliance failures the FDA had specifically identified and the many others Teligent was now expressly warned to

correct – to improve the quality of future ANDA submissions and rebuild its standing with the FDA. This delayed the potential approval of Teligent's already submitted ANDAs, caused the submission of its new ANDAs to slow to an almost complete halt, made the strategy of expanding into new business lines impossible to implement, and resulted in a waste of Teligent's high R&D and other expenses, which the dwindling pipeline could not earn sufficient revenue to cover.

(b) Moreover, they concealed the September 2016 483 Letter, accompanying EIR (defined below), and subsequent follow-up letter from the FDA, which contained observations of multiple, systematic compliance failures in Teligent's procedures and laboratory controls and undermined the integrity of the data that Teligent was submitting in support of its ANDAs. They concealed that information notwithstanding that their own (undisclosed) follow-up letter to the FDA in October 2016 stated that "***Teligent takes these observations extremely seriously***." [Emphasis added]. As set forth herein, responding to those observations and warnings required a substantial amount of Teligent's already overtaxed resources, both for the ANDAs already submitted and prospective infrastructure fixes, thereby delaying the approval of existing ANDAs, delaying the submission of new ANDAs, and limiting Teligent's ability to execute its business plan. This further showed that Teligent was already experiencing serious regulatory problems with its core products, and was not prepared or positioned to expand into new business lines.

11. The truth was revealed for the first time on November 6, 2017, after trading hours. For example, on that day, Defendants disclosed a sharp decline in Teligent's pipeline of new drugs, along with delays in that pipeline, manufacturing challenges, and products that were slow to launch. Defendants also revealed that this had caused reduced revenue, margin, and guidance.

12. The market reacted swiftly and negatively to the disclosures. As a consequence, on the next trading day, November 7, 2017, the price of Teligent common stock dropped 43.62%, from $5.25 per share to $2.96 per share, on a volume of 8.35 million shares.

13. Today, Teligent' stock price is at $0.61, and the Company has been told that, at that level, it is in danger of being de-listed from the Nasdaq Global Select Market ("Nasdaq").

II. JURISDICTION AND VENUE

14. The claims asserted herein arise under §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the Exchange Act (15 U.S.C. §78aa).

16. Venue is proper in this judicial District pursuant to 28 U.S.C. §1391(b) and §27 of the Exchange Act (15 U.S.C. §78aa(a)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud occurred in this judicial District. Many of the acts charged herein, including the preparation and dissemination of materially false and/or misleading information, occurred in substantial part in this judicial District.

17. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the U.S. mail, interstate telephone communications, and facilities of a national securities exchange.

III. PARTIES

18. Lead Plaintiff Oklahoma Police, as set forth in its certification (ECF No. 17-2), purchased Teligent common stock during the Class Period and suffered damages, as a result of the federal securities law violations and false and misleading statements alleged herein.

19. Defendant Teligent is a Delaware corporation with its principal executive offices located at 105 Lincoln Avenue, Buena, New Jersey 08310. During the Class Period, Teligent, through its officers and directors, published periodic filings with the SEC and made public statements that, as alleged herein, violated the securities laws and contained materially false and misleading statements.

20. Defendant Grenfell-Gardner was, at all relevant times, Teligent's President and CEO. Throughout the Class Period, Grenfell-Gardner made statements in the Company's press releases, earnings conference calls, and at other public events, which, as alleged herein, violated the securities laws and contained materially false and misleading statements. At all relevant times, Grenfell-Gardner made the false and misleading statements with scienter.

21. Hereinafter, Defendants Teligent and Grenfell-Gardner will be collectively referred to as "Defendants."

IV. SUBSTANTIVE ALLEGATIONS

A. Factual Background

1. Overview of Defendants' Rush to Grow Teligent's Product Pipeline and Transform its Business, which Resulted in Systematic Failures to Comply with Required FDA Regulations

22. Prior to the Class Period, as the FDA found and Defendants knew, Teligent systematically failed to comply with regulatory requirements on which its entire business rested. Teligent develops generic treatments, primarily topical ointments and lotions, that it can only market if it demonstrates, through data-heavy submissions known as "ANDAs," that it has complied with stringent controls and procedures that ensure both the safety of the treatments and integrity of the supporting data.

23. In fact, Teligent's business model requires a continuously growing pipeline of ANDA submissions and enables the efficient approval of each submission. Since there is little to

distinguish Teligent's generic ointments and lotions from competitors' products, the Company's ability to profit depends primarily on marshaling a large number of low-margin products, and also on attempting to be one of the first generics in a market so that it can earn higher margins until competitors eventually bring prices down.

24. Defendant Grenfell-Gardner led a radical overhaul of the Company in an attempt to generate the required ANDA pipeline. When he joined as CEO, in July 2012, the Company was called IGI Laboratories, Inc. ("IGI"). It had historically manufactured pharmaceutical products for third-party customers, which then sold those products under their own brands. But, beginning in 2010, the Company began to transition from relying on that practice (known as "contract services") as its sole revenue source to also developing its own topical generic pharmaceutical products that it would manufacture and sell under its own brand. The Company's initial attempts to develop its own products moved slowly – in each of 2010, 2011, and 2012, it submitted only two to three ANDAs per year. By April 2014, Grenfell-Gardner announced that he was attempting to dramatically accelerate the Company's transformation and pipeline:

> ***2014 is a year of transformation in IGI, as we accelerate our business and solidify the foundation for future growth.*** Remember that in 2013 we transitioned our business from relying solely on Contract Services by introducing four IGI labeled generic topical pharmaceutical products[.]
>
> * * *
>
> ***Now, we're set on moving even faster to transform our business***, and we remain dedicated to our mission to become one of this [*sic*] top five leading companies in the generic topical pharmaceutical industry. Now, as we set out our plans for this transformational year, I set forth three key goals for IGI. First, revenue growth between 40% and 45%; second ***at least 10 ANDA filings with the FDA for generic topical pharmaceutical products; and third, maintaining profitability in 2014***, while at least doubling our R&D spend to drive shareholder value.

[Emphasis added]. Reiterating that point, on the Company's website, Grenfell-Gardner's biography states that his role is "***leading [Teligent's] transformation into an R&D-centered pharmaceutical company***." [Emphasis added].

25. Defendants' plan to reorient the Company around R&D that would support an accelerating pipeline of ANDA submissions came, however, with a demanding prerequisite for success: they would have to build a development and production infrastructure that satisfied the FDA's stringent regulations for generic products. Since the FDA has already approved generics copy innovator treatments, the supporting data for ANDA approval must convincingly show that the generic has the same characteristics as, works in the same way as, and can consistently be produced to replicate the innovator drug it is copying. To that point, ANDA stands for *Abbreviated* New Drug Application, indicating that in most instances, it does not require clinical data directly demonstrating a generic's impact on patients. In contrast, the FDA requires the submission of such clinical data for the approval of innovator drugs as part of a *New* Drug Application (or "NDA"). As a result, the data supporting ANDA submissions is overwhelmingly produced in laboratories, which are supposed to run a battery of carefully calibrated nonclinical tests to establish that the generic is safe, overlaps with the already approved innovator, and is properly produced.

26. The FDA does not simply accept the data submitted in support of ANDAs. Rather, it requires a showing that the generic producer is following strict laboratory and production controls to ensure the integrity of the supporting data and the safety of the prospective product. Thus the standard for ANDA approval – which is contained in Title 21, Chapter I of the C.F.R. ("Chapter I") – specifically states that the "***FDA will refuse to approve an ANDA***" if, among other things, "***[t]he methods used in, or the facilities and controls used for,*** the manufacture,

processing, and packing of the drug product ***are inadequate to ensure and preserve its identity, strength, quality, and purity***." 21 C.F.R. §314.127(a)(1) [emphasis added].

27. In turn, Chapter I sets forth the "***minimum***" methods and controls that the generic producer must follow to "***assure***" that a treatment for human consumption has the safety, identity, and other characteristics that the treatment "***purports or is represented to possess***." 21 C.F.R. §210.1(a) [emphasis added]. Those minimum methods and controls are collectively referred to as the "***Good Manufacturing Practice***," "GMP," or "cGMP" and defined to include "***testing***" and "***quality control***," as well as an entire subsection with additional "laboratory controls." 21 C.F.R. §§210.3(b)(12) & 211.160-176 [emphasis added]. Moreover, Chapter I sets forth additional general methods and controls that the producer of any treatment, whether for human consumption or otherwise, must comply with, referred to as the "***Good Laboratory Practice for Nonclinical Laboratory Studies***," or "GLP." 21 C.F.R. §58 [emphasis added]. They specifically govern "***nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products***," that is ANDAs, and are "***intended to assure the quality and integrity of the safety data filed***" therewith. 21 C.F.R. §58.1(a). Further, the FDA requires that producers follow specialized methods and controls when running certain complex tests supporting ANDAs, such as the test establishing the "bioequivalence" or overlap between the generic and the innovator, to ensure the integrity of the resulting data. 21 C.F.R. §320.

28. To win ANDA approvals, a generic producer must accordingly demonstrate that it generates the supporting data and relevant products in conformance with the foregoing regulations. That in turn requires generic producers to generate that data through procedures and controls (SOPs) mandated under the GMP. The purpose of SOPs is to assure drug quality, identity, and purity – which means having and following appropriate SOPs is a requirement for ANDA

approval. 21 C.F.R. §§211.100(a), 314.127(a)(1). SOPs are required for laboratory and production controls, such as product specifications, testing, sampling plans, and the handling of products to prevent contamination. 21 C.F.R. §§211.80(a), 211.160, 211.166. GLP also separately requires SOPs. 21 C.F.R. §58.81. Standard SOPs require the tracking of deviations from specifications, investigations into such deviations, and reporting of corrective action to a company's management. Creating and following SOPs imposes a substantial burden on pharmaceutical firms. For example, the FDA estimated the annual record-keeping burden of 21 C.F.R. §211.100(b) alone (requiring that compliance with written procedures be documented at time of performance and that any deviations be recorded and justified) to be 25,104 hours. Creating 25 new SOPs might, per the FDA's estimation, take 20 hours per person and 50,000 hours in one year. (Rules and Regulations, 76 Fed. Reg. 188 (Sept. 18, 2011)).

29. But Defendants did not provide the substantial infrastructure, in terms of staff or required control systems, necessary to satisfy those demanding regulations as they attempted to significantly scale-up the Company's core topical ANDA submissions. Instead, Defendants diluted the Company's limited resources by, also beginning in 2014, attempting to simultaneously launch a series of new businesses:

(a) First, the Company would attempt to develop injectable, complex, and ophthalmic generic drugs in addition to topicals. Defendants used the acronym "TICO" for each of the four product lines to refer to this "broader strategy." Acknowledging that there was comparatively more competition in the markets for topical generic treatments, which tended to be simpler products, Defendants were seeking better returns with the other product lines.

(b) Second, to familiarize themselves with the three new lines of generic treatments, and because the Company's own pipeline of topical ANDAs was not producing significant revenue, Defendants began purchasing a large number of ANDAs or the rights thereunder. After acquiring one topical ANDA in 2013, they acquired 20 ANDAs and NDAs in September 2014, almost all of which were for injectable drugs.

(c) Third, the Company planned to significantly expand its headquarters in Buena, New Jersey (the "Buena Facility"), where it had facilities for R&D, nonclinical laboratories, and manufacturing, along with executive offices. Defendants intended to begin construction in late 2015 and complete it in 2017. This would increase the facility's topical manufacturing capacity and also create the ability to produce and sell the more complex products in the TICO strategy. For example, the expansion would include a sterile facility that was required to manufacture injectable treatments. Producing injectables through third-party manufacturers was generally cost-prohibitive, so, without that facility, Teligent could not sell them or implement the TICO strategy.

30. Defendants emphasized how radical this planned overhaul was by changing the Company's name to "Teligent" in October 2015, but their efforts achieved little lasting impact beyond putting an impossible number of demands on overburdened employees and saddling it with enormous, unjustified expenses. In 2016, after several years of growth, Teligent still only had about 150 employees. Meanwhile, Teligent's R&D costs more than doubled, from approximately $2.8 million in 2012 and 2013 to over $6.9 million in 2014, in an attempt to fuel its pipeline of ANDA submissions. That expenditure was enormous, particularly for a small company, equaling over 20% of Teligent's total revenues. R&D costs continued to balloon over the following years, reaching over $17 million and approximately 26% of total revenue in 2016. Moreover, in 2016,

Teligent spent $13.5 million on capital expenditures related to its facility expansion, only about 25% of the expected $55 million cost and its expenses for Selling, General & Administrative ("SG&A") functions had increased from $3.1 million in 2012 to $15 million in 2016, as Defendants tried to build a sales infrastructure for the ANDA pipeline they were supposedly growing.

31. Throughout all of that, Defendants repeatedly assured investors that their heavy investment in R&D was successfully driving Teligent's rapid transformation. As Grenfell-Gardner stated in an April 2016 conference call, ***ANDAs were "the key to Teligent's growth***[.]" [Emphasis added]. Similarly, on March 7, 2017, the start of the Class Period, Grenfell-Gardner claimed that "***[w]e're not so much playing defense trying to protect our installed markets, but rather playing offence as we launch new drugs into the market.*** That's why if you compare our results to those of our peers, a few key differentiators stand out. First, ***we invest significantly more in R&D and we get significantly more out of it***." [Emphasis added].

32. Though Defendants' acceleration plan did allow Grenfell-Gardner to state that Teligent had submitted 11 ANDAs in 2014, 15 ANDAs in 2015, and 12 in 2016, up from about 2 to 3 several years earlier – as the FDA found – those submissions were illusory. The Company achieved this dramatic increase only by cutting corners and systematically failing to comply with the demanding GMP, GLP, and other regulations discussed herein. Over the course of three inspections, as detailed below, the FDA found that Teligent failed to ensure data and product integrity, including by failing to investigate or reject out-of-specification results, have or follow appropriate SOPs, keep records, validate methods, and prevent contamination.

33. Significantly, Grenfell-Gardner knew that the FDA had reached such negative findings well before the Class Period started. For example, the FDA inspected Teligent in

September 2016, about six months before the Class Period. Following the inspection, the FDA sent a series of letters and other official documents discussing Teligent's regulatory failures between September and February 2017 that were addressed to Grenfell-Gardner and/or noted that all FDA correspondence were to be addressed to him. One of those was a Form 483 Letter, which the FDA issues to firm management after an inspection when the "conditions or practices observed would indicate that any food, drug, device or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health." FDA inspectors are trained that all 483 observations are to be "clear, specific, and significant."

34. Of course, Grenfell-Gardner did not need the FDA to tell him that Teligent was systematically failing to comply with required regulations. He was the CEO of a small company, whose office was in the same complex as Teligent's plant where the violations occurred; his direct-reports included the Chief Scientific Officer, Plant Manager, and Senior Vice President of Quality Control; and Teligent tracked out-of-specification results and non-conformance reports which evidenced the compliance failures.

35. Moreover, those failures were a direct extension of Grenfell-Gardner's attempt to rapidly transform and expand Teligent's business, at a massive expense, prior to and during the Class Period. Fulfilling all of the time consuming regulatory requirements designed to ensure product safety and to properly grow a pipeline of topical ANDAs would have required enormous resources, which Teligent did not have and Grenfell-Gardner diverted to the new business lines in any event. So, Teligent simply failed to follow those requirements at virtually every phase of the generic development process. As documented by the FDA, and detailed below, Teligent's corner-cutting practices and widespread compliance failures included: failures to implement and follow

required SOPs and other laboratory controls, failures to properly administer required tests and studies, failures to investigate tests and studies that yielded OOS results, and failures to store required data and records. Also contributing to these failures, as Teligent eventually admitted to the FDA, it had badly understaffed the Quality Control department that was supposed to prevent them. In the short-run, the foregoing practices dramatically sped up Teligent's ability to submit ANDAs between 2014 and 2016; but shortly thereafter, and by the start of the Class Period in March 2017, they caused Teligent's pipeline to shrink and its ANDA submissions to fall back to their "pre-transformation" levels.

36. The foregoing systematic misconduct was not only documented by the FDA, but was also described by Confidential Witness ("CW") 1, who worked for Teligent in its facility as an investigations scientist throughout the Class Period, from approximately July 2016 to February 2018. CW1 was in the Quality Control group and initially reported to Quality Control Manager Ahmer Ali, and later reported to Vice President of Quality Control Barbara Lani ("Lani"), who, in turn, reported directly to Defendant Grenfell-Gardner.

37. A lack of staff assistance, coupled with unrealistic deadlines, caused serious back-ups in Teligent's work during CW1's tenure at the Company, which ran from before the Class Period started to after it ended. CW1 stated that there were enough staff members to conduct basic testing, but there was no help to conduct data analysis or investigations and that the lack of staff and resources affected Teligent's Quality Control, where many people in the department were overwhelmed.

38. Accordingly, though the SOP within the industry was for Quality Control to try to close investigations into tests yielding an incorrect specification (*i.e.*, OOS) within 30 days of

receiving such results, CW1 explained that doing so was impossible at Teligent. That was because CW1 often had between 30 and 40 open investigations at any one time.

39. However, CW1 was pressured to close cases or investigations, regardless of outstanding issues, so that Teligent could submit its ANDA to the FDA, or so that products could be manufactured and shipped. CW1 explained that an ANDA could not be filed with the FDA until everything – meaning every investigation and/or non-conformance report ("NCR") – was "closed." As such, Teligent's management regularly decided to declare investigations "closed" prematurely. CW1 stated that the pressure was put on CW1 directly by Vice President of Quality Control Lani and General Manager Troy Woelfel ("Woelfel"), both of whom were direct reports to Grenfell-Gardner.

40. Moreover, CW1 stated that management put intense pressure to submit a high volume of ANDA filings on timelines which were unrealistic, given Teligent's lack of resources.

41. Attempting to submit a high volume of ANDAs at such a high speed led to mistakes being made. Those mistakes often caused OOS test results, which, in turn, triggered investigations into those results, which caused further back-ups.

42. CW1 was also aware that Teligent's sterile manufacturing facility was significantly behind on its development timeline.

43. In sum, Teligent's entire business model depended on cutting corners in the development of new products, so that it could rush out ANDA submissions and, in turn, Grenfell-Gardner could tout the Company's increasing pipeline of ANDAs as a purported sign of the Company's success, when, as the FDA found, Teligent actually lacked the compliance infrastructure necessary to support that pipeline.

2. FDA Investigations and Letters Showed that Prior to, During, and Following the Class Period, Teligent Systematically Failed to Comply with Required Regulations for Generic Producers

44. Over three successive investigations at Teligent's Buena Facility, the FDA informed Grenfell-Gardner and his direct reports of widespread compliance failures in the nonclinical laboratory and production practices on which its ANDA submission pipeline depended. The first pertinent investigation occurred in September 2016, several months before the Class Period started, the second occurred toward the end of the Class Period in October 2017, and the third occurred after the Class Period in April and May 2019.

45. The compliance failures at issue in each investigation involved substantially similar issues that arose from Teligent's rushed, unfocused, and understaffed operations. In particular, Teligent failed to: adopt or follow required SOPs and controls; properly conduct required tests and studies; investigate at all, or to investigate adequately, tests and studies that generated OOS results; and store required data and records. These failures undermined the integrity of the data that Teligent submitted in support of its ANDAs to the FDA. The FDA's investigations also show that Teligent was engaging in all of those impermissible practices before and during the Class Period. Moreover, these failures were so deeply ingrained in Teligent's practices that it was unable to fix them despite the regularity of the FDA investigations occurring about every 12 months from 2016 to 2019.

46. Following each investigation, the FDA reported its findings to Grenfell-Gardner and his direct reports. In each case, the FDA issues what is known a Form 483 or a 483 Letter. As set forth on the FDA's website, these are "issued ***to firm management*** at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations" of the applicable statute and regulations. The 483 Letters set out these conditions in the form of numbered observations. FDA inspectors know that each 483 observation

must be "***clear, specific and significant***." [Emphasis added]. A 483 Letter "***does not include observations of questionable or unknown significance at the time of the inspection.***" [Emphasis added]. Moreover, a 483 Letter is explicitly for a firm's senior management: at the end of an inspection, the inspector will discuss each observation "***with the company's senior management***[,]" so that "***there is a full understanding of what the observations are and what they mean.***" [Emphasis added]. Following at least the first two investigations, the FDA also issued an Establishment Inspection Report ("EIR"), which elaborates upon the observations in the 483 Letters, described discussions with senior management, and included other comments from the inspector. In addition, following at least the first investigation, the FDA sent a follow-up letter to Teligent emphasizing its compliance failures. For its part, after receiving each 483 Letter, Teligent responded to the FDA by setting forth, in writing, burdensome and widespread corrective action plans that it promised to implement.

a. The FDA's September 2016 483 Letter

47. The FDA conducted an unannounced "pre-approval" inspection at the Buena Facility in response to an ANDA submission from Teligent. This took place between September 12 and 16, 2016, and was conducted by the "***Office of Study Integrity and Surveillance***" from the FDA's Division of Generic Drug Bioequivalence Evaluation. [Emphasis added]. Following the inspection, the FDA issued a 483 Letter and accompanying EIR citing multiple compliance failures by Teligent (the "September 2016 483 Letter").

48. These compliance failures were significant because they showed that Teligent's practices, including in its critical laboratories, systematically undermined the integrity of the data that Teligent was submitting in support of its ANDAs.

49. *First*, three of the 483 observations showed that Teligent was conducting tests required for ANDA approval in a fundamentally flawed manner. For example:

(a) the method for measuring certain "***concentrations in study samples used only a single concentration . . . that was not representative of the range of . . . concentrations***" at issue and "***no separate quality control samples were used to evaluate [the] accuracy and precision***" of the test (Observation 3) [emphasis added];

(b) again, "***[q]uality control samples representing the range***" of certain concentrations at issue were also "***not included in the HPLC analysis***," which stands for "high-performance liquid chromatography" and identifies and quantifies a material's component parts (Observation 4) [emphasis added]; and

(c) the stability studies on certain solutions were "not evaluated with a fresh calibrator solution[,]" meaning that Teligent did not run quality control checks against the full range of characteristics that the solution may have and, when running the study, did not refresh the calibrator solution with samples representing that full range (Observation 5).

50. *Second*, two of the 483 observations showed that Teligent was not storing data and records that were supposed to substantiate the information submitted to the FDA in support of ANDAs. For example:

(a) "***[t]he firm did not randomly select and retain reserve samples***" from product samples it was testing to show that the product purportedly was bioequivalent to the innovator treatment it was attempting to copy (Observation 1) [emphasis added]; and

(b) "***[t]he drug accountability records***" for the sample products used in the bioequivalence studies "***were insufficient to reconstruct the receipt, storage, handling, and use of these products***" (Observation 2) [emphasis added].

51. The EIR repeated and expanded on the 483 observations, explaining that they resulted from a complete absence of required SOPs. Under the section titled "***Facilities and Site Operations***" [emphasis added], the EIR firmly concluded that:

(a) "***[t]he SOP program is not adequate and current to ensure quality in analytical operations*** and the generated in-vitro study data" [emphasis added]; and

(b) "***[t]he sample receipt and accountability processes were not adequate to ensure the integrity of the sample usage*** during the study." [Emphasis added].

It elaborated that "***[t]here were no SOPs for reserve samples, sample accountability and storage of drug products***" and that "***[t]he firm does not have a standard operating procedure for sample receipt and accountability***." [Emphasis added].

52. Teligent's compliance failures described in the preceding paragraphs implicate the GMP, GLP, and other pertinent regulations. As examples, the Lab Controls and Production and Process Controls sections of the GMP prohibit Teligent's use of unrepresentative samples in its studies (Observations 3 and 4), Teligent's undertaking unreliable stability tests (Observation 5), and its failure to have SOPs (EIR comments). *See*, *e.g.*, 21 C.F.R. §§211.100(a), 211.165(e), 211.166(a)(3). The Lab Controls and Production and Process Controls sections of the GMP, GLP, and other regulations, prohibit Teligent's failure to store reserve samples and have SOPs for such storage (Observation 1 and EIR comments). *See*, *e.g.*, 21 C.F.R. §§58.105(d), 58.195, 211.100(a), 320.38, 320.63. The GLP also prohibits Teligent's failure to keep drug accountability records (Observation 2). *See*, *e.g.*, 21 C.F.R. §58.107.

53. On October 5, 2016, Teligent sent a letter to the FDA regarding the foregoing 483 observations. The letter stated that "***Teligent takes these observations extremely seriously***[.]"

[Emphasis added]. Further, "***Teligent realizes that any FDA inspection is limited in its scope, and therefore, the observations cited may not be all inclusive***." [Emphasis added].

54. Teligent accepted the FDA's findings. The letter acknowledged that Teligent used "***inappropriate***" test methods, that it "***failed to use quality control samples***" to appropriately check tests, and that it had a "***gap***" in its SOPs. [Emphasis added].

55. Although Teligent promised to fix its compliance failures, doing so would require a commitment of significant resources. Thus, Teligent promised to draft and implement multiple new SOPs and to repeat the in-vitro bioequivalence study it had previously submitted in support of an ANDA under new and much more rigorous protocols.

56. The FDA responded with a letter of its own, addressed to "***Jason Grenfell-Gardner***," and dated February 21, 2017. It began, "***[t]his letter informs you of objectionable conditions observed during the U.S. Food and Drug Administration (FDA) inspection conducted at Teligent Pharma, Inc., from September 12 to September 16, 2016***." [Emphasis added]. Significantly, the FDA letter then stated:

> From our review of the FDA Establishment Inspection Report, the documents submitted with that report, and your written response to the Form FDA 483, ***we conclude that you did not adhere to the applicable statutory requirements and FDA regulations*** governing the conduct of BE studies. We wish to emphasize the following:
>
> ***You failed to meet the regulatory requirements for retention of reserve samples for bioavailability or bioequivalence studies*** **[21 CFR 320.63 and 320.38].**

[Emphasis added and in original]. The FDA explained that this "***raises concerns about the validity and integrity of the studies conducted at your study site***." [Emphasis added].

57. Finally, it warned Grenfell-Gardner that as "[t]his letter is ***not intended to be an all-inclusive*** list of deficiencies":

> ***You are responsible for ensuring that your site adheres to all requirements of law and all FDA regulations*** that are relevant to studies of FDA-regulated products

> conducted at your site. ***You should address these deficiencies and establish procedures to ensure that any ongoing or future studies will be in compliance with FDA regulations.***

[Emphasis added].

58. This FDA letter was just one of several instances where the FDA conveyed its substantial negative findings to Grenfell-Gardner, as well as other senior Teligent management, in 2016 and early 2017. The EIR also stated that FDA correspondence concerning Teligent, including with regard to the 483 Letter, should be "***addressed to: Mr. Jason Grenfell-Gardner, President and CEO.***" It further recounts that at the end of the inspection, the FDA inspector discussed the observations in the 483 Letter and the EIR with senior Teligent executives, including Steve Richardson, the Chief Scientific Officer and a direct report to Grenfell-Gardner, and others involved in quality control, quality assurance, and analytics.

b. The FDA's October 2017 483 Letter

59. The FDA conducted another inspection at the Buena Facility in response to ANDA submissions from Teligent, to surveil the GMP compliance of the Facility, and in response to Field Action Report related to a product recall. This took place over 11 days between October 2 and October 19, 2017. Following the inspection, the FDA issued another 483 Letter and accompanying EIR citing multiple compliance failures by Teligent (the "October 2017 483 Letter").

60. Again, those failures, as described in five 483 observations, were significant because they showed that Teligent's absence of procedures and controls, including in its critical laboratories, systematically undermined the integrity of the data Teligent submitted in support of its ANDAs. To that point:

(a) "***Laboratory controls do not include the establishment of scientifically sound and appropriate specifications designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity***" – that is, those controls do

not meet the standard for ANDA approval or the minimum requirements of the GMP. (Observation 6) [emphasis added];

(b) Similarly, "***[e]stablished laboratory control mechanisms are not followed***[,]" and, consequently, "***confirmed Out of Specification results are not further investigated as per the laboratory investigation SOP***." (Observation 5) [emphasis added];

(c) Moreover, the "***firm failed to conduct investigations properly for [ANDA] application products***[,]" in particular, where a test or sample "***failed to meet [a] specification***," an "***[i]investigation into [such] failures are not performed or not performed adequately***," which impermissibly leaves the reason for the failure unidentified. As "***[e]xamples***[,]" the 483 listed three ANDAs where this had occurred and at least two of the cited instances occurred in 2015 or 2016, well before the Class Period started. (Observation 2) [emphasis added];

(d) Further, Teligent's "***[t]esting and release of drug product [sic] do not include appropriate laboratory determination of satisfactory conformance to the final specifications***." The 483 elaborated by describing an incident where this had occurred for "***submission batches***" of a potential product that Teligent provided to the FDA in support of an ANDA. (Observation 4) [emphasis added]; and

(e) When undertaking certain required tests, Teligent also used test methods the suitability of which "***have not been established***[,]" which called into question the data generated therefrom. Here too, as "***[e]xamples***[,]" the 483 listed three ANDAs where this had occurred and all three of the cited instances occurred in 2015 or 2016, well before the Class Period. (Observation 3) [emphasis added].

61. In addition, one 483 observation described "***a failure to handle materials in a manner to prevent contamination***" in violation of the GMP. [Emphasis Added]. It involved an incident, in 2016, where Teligent's manufacturing process permitted the contamination of a product, and though aware of this contamination, Teligent allowed a "Lot" of the resulting product to be shipped into interstate commerce. (Observation 1).

62. The FDA also issued a 48-page EIR expanding on the observations in the October 2017 483 Letter, as well as other problems in Teligent's laboratory and production practices. The FDA described Teligent's failure to conduct appropriate investigations for numerous "exhibit batches" upon which the tests generating data for ANDAs are run, including into OOS results those batches exhibited. The inspector further noted that Teligent's own SOP required investigation into root causes of OOS results, but despite this, for the "pre-approval application," Teligent did not conduct such investigations. In other words, Teligent was just confirming the existence of OOS results in exhibit batches and then declaring the investigation closed without performing an associated manufacturing investigation into why and how the failures came to be. This pretense allowed Teligent to hastily submit ANDAs without going through the required process of performing full and meaningful investigations into failures. The EIR further reflects that Teligent had a large number of failures requiring investigations in 2016 and 2017.

63. Teligent's compliance failures described in the October 2017 483 Letter implicate the GMP, GLP, and other pertinent regulations. As examples, the Lab Controls and Production and Process Controls sections of the GMP prohibit Teligent's failure to conduct root cause investigations into OOS results and failure to follow its own SOPs in so doing (Observations 2 and 5); Teligent's failure to validate methods before using them (Observation 3); Teligent's failure to determine conformance of drug products to specifications (Observation 4); and Teligent's failure

to have laboratory controls, including the establishment of scientifically sound and appropriate specifications designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity (Observation 6). 21 C.F.R. §§211.100(b), 211.160(b), 211.165(e), 211.192. The Component Control section of GMP prohibits Teligent's failure to handle materials in a manner to avoid contamination (Observation 1). 21 C.F.R. §211.80(b). The GLP also prohibits Teligent's violation of SOPs without appropriate authorization and documentation. 21 C.F.R. §58.81.

64. The compliance failures cited in the October 2017 483 Letter were also systematic Teligent practices that dated back to before the Class Period. The October 2017 483 Letter described several of those practices going back to 2015 or 2016, as set forth above, and Teligent admitted that several of those practices dated back at least that far in its written response to the Letter, as set forth below.

65. Likewise, CW1, whose job responsibilities involved investigating OOS test reports on products, described practices at Teligent throughout and before the Class Period that were similar to those set forth in the October 2017 483 Letter. With regard to OOS samples, CW1 stated that, while at Teligent, CW1 worked on about 400 investigations, out of which "dozens" involved pressure by Lani and Woelfel (the head of Quality and the General Manager/Plant Manager, respectively, who were Grenfell-Gardner's direct reports) to close the investigations out before CW1 was comfortable and felt that the investigation was complete.

66. CW1 stated that Teligent's process for dealing with NCRs and related issues, which included investigations of OOS results, was not fully in place or established when CW1 joined the Company prior to the Class Period in July 2016. After Teligent's Quality Control analysts conducted tests of products, if any of the product samples tested did not conform to their

specifications, then the analysts would submit a report to CW1. CW1 would conduct the investigation to determine why the product failed the test, attempt to determine the root cause, and recommend corrective actions. Teligent had certain SOPs, which matched FDA guidelines, to determine the directly assignable cause for why the product was OOS. The SOP for investigation included, among other things, checking the equipment used to conduct the test to make sure it was functioning properly and correctly "validated"; checking the preparation of the test sample itself; checking the instruments used to prepare the sample for testing; and checking that the testing procedures were followed correctly. If these steps did not determine the cause, the investigation would become wider, including testing more samples. Once the investigation was complete and CW1 had determined the most likely root cause, CW1 would prepare a report and create a Corrective Action Plan. If the root cause was determined to be a production or process problem, then a NCR was issued.

67. However, CW1 explained that because an ANDA could not be filed with the FDA until everything – meaning every investigation and/or NCR – was "closed," Teligent's management regularly decided to declare investigations "closed" without definitively determining what the root cause of the OOS result was. For example, instead of completely proving that the test result was due to analyst error, CW1 was pressured to close the case by declaring it was "undetermined error" by the analyst. In other words, CW1 had to declare the most likely root cause, instead of fully investigating the situation to determine the precise root cause.

68. Further, CW1 was generally aware that there were a large group of NCRs that had been created in the autumn of 2017, though CW1 could not connect them specifically to the FDA inspection during that time. CW1 explained that many of the NCRs were retroactive and related to issues that had been persisting for some time, including pre-dating CW1's employment at

Teligent in July 2016. Many of the issues involving OOS samples had been flagged in the NCRs and assessed as production issues, but were not being addressed. CW1 stated that these issues were left open for a very long time and should have been written up into NCRs earlier.

69. When CW1 had initially been hired, the manager who hired CW1 created the impression that role would largely involve supervision of other investigation scientists, but in reality, CW1 was the only scientist conducting the actual investigations and was overwhelmed. CW1 believed that the problem of backlogged NCRs and related issues was because Teligent's Quality Control department was under-resourced.

70. On November 6, 2017, Teligent wrote the FDA in response to the October 2017 483 Letter. Teligent acknowledged all of the observations in that Letter and the additional issues in the accompanying EIR. Significantly, for example, Teligent admitted the accuracy of the FDA's observations (2 and 5) that "[i]nvestigation into [OOS] failures are not performed or not performed adequately," and that "Out of Specification results are not further investigated as per the laboratory investigation SOP" to determine their root cause. As Teligent noted, its practice during and before the Class Period was that "***quality control (QC) laboratory out of specification (OOS) investigations of Exhibit batches were concluded when the OOS results were confirmed; no manufacturing investigation***." [Emphasis added]. All that happened was the "***findings of the OOS investigation was reported to the R&D team for further evaluation and action, but no follow up was deemed required by QA [quality assurance] or QC***." [Emphasis added]. However, as described above, this effectively swept the investigation under the rug and deemed the investigation closed for the purpose of the ANDA application, so that the ANDA could be impermissibly submitted to the FDA notwithstanding the OOS result. Teligent also employed the "***same***" impermissible practice "***for deviations during manufacturing that were not investigated***

immediately by the production department[.]" [Emphasis added]. Similarly, with respect to the FDA's Observation 3 that Teligent used test methods the suitability of which "have not been established[,]" Teligent acknowledged that prior to the October 2017 483 Letter, it did not have an SOP to "***ensure that any laboratory test method being used in the laboratory has been previously validated or verified***." [Emphasis added].

71. Attempting to salvage its standing with the FDA, by correcting its many compliance failures and the ripple effects they caused, would take a substantial commitment of Teligent's scarce resources. To that point, Teligent went on to write that it was updating many of its SOPs to bring its practices into regulatory compliance prospectively. As noted, simply updating SOPs was a burdensome, expensive, and time-consuming process: the FDA estimated that it would take "20 hours per record-keeper" to create 25 new SOPs for a total of 50,000 hours, which does not include the time and expense of implementation. Additionally, to address the many problems in the ANDAs it had already submitted, Teligent would take a host of corrective actions, including: reviewing NCRs since January 1, 2016, and retroactively updating them, redoing tests, or performing necessary tests for the first time, reviewing all OOS for all pending ANDAs, and reopening investigations.

72. According to Teligent, it would attempt to accomplish all of these prospective and corrective actions in just five months, which would divert badly needed resources that it would otherwise use to develop its pipeline of new ANDA submissions. Not to mention that Teligent would have to try to develop those ANDAs in a more time consuming, rigorous, and compliant manner. Illustrating the conflict between, on the one hand, correcting old ANDAs and longstanding compliance failures, and, on the other hand, developing new ANDAs, on November 19, 2017, Teligent received a "major complete response letter" for one of the ANDAs discussed

in the October 2017 483 Letter. The ANDA in question involved an inadequate investigation into OOS (Observation 2), and though Teligent said it would respond to the major complete response letter, such a letter means that the FDA has found that the ANDA is unlikely to be approved. Responding to the major complete response letter would require a complete overhaul of Teligent's processes: SOPs, other laboratory controls, production and process controls, training, and hiring.

73. Once more, the FDA conveyed its substantial negative findings regarding the October 2017 483 Letter and EIR to Grenfell-Gardner, as well as other senior Teligent management. The EIR again stated that FDA correspondence concerning Teligent, including with regard to the 483 Letter, should be "***addressed to: Mr. Jason Grenfell-Gardner, President and CEO***." [Emphasis added]. It further recounts that at the end of the inspection, the FDA inspector discussed the observations in the 483 Letter and the EIR with senior Teligent executives, including direct reports to Grenfell-Gardner, and that the FDA investigator met with Grenfell-Gardner during the inspection. As such, Teligent's November 6, 2017, response to the FDA listed Grenfell-Gardner as a "cc."

c. The FDA's May 2019 483 Letter

74. The FDA conducted a third inspection at the Buena Facility of Teligent's "Laboratory Control System," "Quality System," and "Production System." This took place over 10 days between April 22 and May 20, 2019. Following the inspection, the FDA issued a 483 Letter, citing 10 compliance failures by Teligent and that was addressed to "Jason Grenfell-Gardner, President/CEO" (the "May 2019 483 Letter" and collectively, with the September 2016 and October 2017 483 Letters, the "483 Letters").

75. The failures related to the Laboratory Control System, which compromised half of those 483 observations, showed that Teligent's faulty controls, SOPs, and practices, dating back to before the Class Period, still had not changed. Teligent continued to perform tests improperly,

inadequately investigate tests with OOS results, and insufficiently store relevant data and records – the very observations made in the September 2016 and October 2017 483 Letters. These failures remained significant because they systematically undermined the integrity of the data Teligent submitted in support of its ANDAs.

76. Thus, citing numerous "***[e]xamples***," the May 2019 483 Letter observed the following continued compliance failures:

(a) "***Drug products failing to meet established specifications are not rejected***" (Observation 1) [emphasis added];

(b) "***Investigations of a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product***" (Observation 2) [emphasis added];

(c) "***Laboratory records are deficient in that they do not include a statement of the results of tests and how they compare to the established specifications***" (Observation 3) [emphasis added];

(d) "***Written records are not always made of investigations into the failure of a batch or any of its components to meet specifications***" (Observation 4) [emphasis added]; and

(e) "***The written stability testing program [SOP] is not followed***" (Observation 5) [emphasis added].

77. In addition, the May 2019 483 Letter observed other compliance failures related to Teligent's quality and production practices. For example, Teligent failed to submit Field Action Reports on-time or at all for significant OOS results and failed to follow procedures for handling complaints and annual product reviews (Observations 6-8). It further failed to establish control

procedures to monitor manufacturing processes, causing variability in the characteristics of drug products, and to make records associated with drug products available for authorized inspection (Observations 9-10).

78. Teligent's compliance failures described in the May 2019 483 Letter implicate the GMP, GLP, and other pertinent regulations. As examples, the Lab Controls and Production and Process Controls sections of the GMP prohibit Teligent's failure to reject drug products that do not meet specifications (Observation 1); Teligent's failure to extend investigations into OOS results in a batch or any of its components to include other batches of the same drug product (Observation 2); Teligent's failure to include statements in laboratory records as to whether the results met specifications (Observation 3); Teligent's failure to make written records of investigations into OOS results (Observation 4); and Teligent's failure to follow its written stability testing program. 21 C.F.R. §§211.100(b), 211.165(f), 211.166(a), 211.192, 211.194(a)(6).

79. The May 2019 483 Letter is also consistent with CW1's statement that Teligent's many overdue investigations continued after the October 2017 483 Letter and after the Class Period ended. CW1 recounted a meeting with Lani, Teligent's Vice President of Quality Control, which CW1 believed took place in January 2018, regarding those investigations. Lani asked what CW1 needed to get the investigations completed in time, CW1 then asked for more staff and resources, and Lani told CW1 that would not happen.

80. On June 4, 2019, Teligent provided a written response to the May 2019 483 Letter. Teligent acknowledged that, notwithstanding its promises to the FDA following the September 2016 and October 2017 483 Letters, it still had not fixed the compliance failures cited therein. This time, it promised to undertake more radical mediation efforts and to update its SOP yet again, including an overhaul of its root cause investigatory practices for OOS results.

81. More significantly, and consistent with CW1's statements, Teligent admitted that prior to the May 2019 483 Letter – that is during and prior to the Class Period – it lacked sufficient personnel to comply with the Laboratory Controls and other regulations designed to ensure the integrity of data it submitted in support of ANDAs. The June 2019 letter promised that Teligent was finally making a "concerted effort to staff the organization ***appropriately***." [Emphasis added]. Teligent further conceded that "***[a]ll***" of its "***overdue activities***" – including the "***complaint investigations***" – were the result of its serious staffing issues. [Emphasis added]. It then described at length the inadequate staffing of its Quality Control department and related departments, the problems that inadequate staffing caused, and the many additional and senior hires it had to make in order to address those problems, including that Teligent:

(a) had ***not been relying on "permanent employees"*** [emphasis added];

(b) was "***hiring a Quality Compliance Director, who will be responsible for all shop floor and laboratory audits. This staffing addition will not only ensure that all non-conformances are recorded and appropriately investigated, but it will allow us to contemporaneously mentor and coach***" [emphasis added];

(c) had made ***new hires in the "Quality group within the past twelve (12) months and we have hired a new Vice-President of Operations and a new Vice-President of Quality in order to add industry experience, knowledge, and expertise to our organization"*** [emphasis added];

(d) had "***[i]ncreased Quality presence on the floor auditing, training, and mentoring, which will allow for the review of many internal processes and departments, including the laboratories***" [emphasis added];

(e) was nevertheless "***currently analyzing our workload and comparing this data to staffing levels in the laboratory and across the company in order to enhance our visibility to these types of issues***" because of continued compliance failures; and

(f) is "***assembling a stability workload extrapolation matrix that will provide us with the number of analysts required at various production levels***." [Emphasis added].

3. Teligent's Pipeline of ANDA Submissions was Undermined by Its Defective Practices, Attempts to Respond to the FDA's Findings, and Its Failure to Adequately Do so

82. As set forth above, Defendants rushed to submit ANDAs as fast as possible, while making grossly insufficient investments in human resources and laboratory controls. This corner-cutting enabled Teligent to significantly increase its pipeline of ANDA submissions to the FDA in 2014-2016, the years of Grenfell-Gardner's purported "transformation" and before the Class Period began. In turn, Grenfell-Gardner touted Teligent's purportedly growing pipeline of ANDA submissions, which was at least two to three times larger in 2014-2016 than it was in prior years.

83. But, by September 2016, the FDA had observed the corner-cutting Defendants undertook to achieve those illusory results. In three 483 Letters, from September 2016 to May 2019, the FDA observed that Teligent was engaged in persistent regulatory compliance failures, which, prior to and throughout the Class Period, undermined the integrity of the data Teligent submitted in support of its ANDAs. To summarize the discussion above, the 483 Letters showed that Teligent's corner-cutting resulted in the following systematic and substantial impermissible practices:

(a) failures to store required data and records;

(b) failures to conduct required tests using the proper methods;

(c) absent, deficient, or not followed SOPs and other laboratory controls; and

(d) absent or improper investigations and other handling of OOS results.

84. By the time the Class Period started in March 2017, the measures Teligent had to take to respond to the FDA's observations undercut Teligent's ability to submit new ANDAs, and its pipeline of new submissions slowed to a trickle. This happened for several reasons, but, underlying them all was the fact that bringing Teligent's impermissible practices into compliance, and attempting to assure the FDA that the Company's practices generated reliable data, required a substantial commitment of resources and time. Teligent was not able to make such a commitment without diverting resources from its attempts to submit new ANDAs. It was a small company that, as detailed above, already had insufficient staff to address the diverse plans Grenfell-Gardner had sunk resources into, and had already committed substantial amounts of its limited financial resources to expanding the Buena Facility, building out the sales group, and other projects.

85. To begin with, after receiving the September 2016 483 Letter, Teligent had to attempt to save the ANDA submission discussed therein. Accordingly, as noted above, in its written response from October 2016, Teligent promised to divert resources to repeat the supporting studies and tests it had conducted improperly, and to perform them in the more-rigorous, time-consuming and proper manner this time around. This, of course, delayed the approval of those already submitted ANDAs, not to mention the submission of new ANDAs.

86. Next, in order to prevent the various compliance failures observed by the FDA from recurring, in its October 2016 written response, Teligent promised to implement the required SOPs that the FDA had found to be completely absent, inadequate or not followed. Creating new SOPs, training personnel to implement them correctly, and updating laboratory practices accordingly is extremely burdensome: for example, as stated above, according to the FDA's estimates, simply creating 25 SOPs requires 20 hours from each record-keeper. Focusing on these tasks further detracted from Teligent's ability to submit new ANDAs.

87. On top of that because Teligent's October 2016 written response accurately recognized that the September 2016 483 Letter was not "all inclusive," Teligent had to expend resources on addressing its other compliance failures not listed therein, of which there were many. Indeed, until Teligent addressed all of those failures (along with the ones observed by the FDA), it made little sense for Teligent to invest significant resources in submitting new ANDAs because it would just have to redo the underlying tests and studies later if and when it could undertake them in a compliant manner.

88. Moreover, one of the fundamental causes of Teligent's longstanding compliance failures was its deeply inadequate staffing, as it eventually admitted to the FDA in 2019. But, as both CW1 and Teligent relayed, Teligent did not invest the resources necessary to deploy adequate staffing until well after the Class Period ended (and perhaps not even then). That is, Teligent did not have sufficient staffing to satisfy its remedial promises to the FDA and simultaneously submit new ANDAs.

89. Fixing its compliance failures, and essentially implementing entirely new SOPs for critical practices, proved too great a task for Teligent to undertake, which led to the October 2017 and May 2019 483 Letters, during and after the Class Period. As set forth above, with each new 483 Letter, Teligent promised to take increasingly burdensome prospective steps, and to redo tests and studies for yet more ANDAs it had already submitted that were now in danger of denial. This continued to divert resources from new ANDA submissions not just prior to and during the Class Period, but also long after the Class Period ended.

90. Consequently, Teligent's compliance failures and response thereto resulted in Teligent's new ANDA submissions grinding to a virtual halt during and after the Class Period. Compared to the 11 ANDAs it submitted in 2014, 15 ANDAs submitted in 2015, and 12 ANDAs

submitted in 2016: Teligent managed only 4 ANDA submissions in 2017. That brought Teligent all the way back to its low submission levels from before 2014, before Grenfell-Gardner implemented his illusory "transformation" plan. Burdened by its continuing compliance failures, Teligent has remained at those low submission levels following the Class Period: it submitted only 3 ANDAs in 2018, and has not announced a single ANDA submission for 2019, as of the date of this filing (December 9, 2019). This sharply diminishing pipeline occurred despite massive increases in R&D and other expenses, as discussed above. In sum, Teligent is expending substantially more money on a dwindling ANDA pipeline that is, in turn, not large enough to recoup those expenses.

91. As set forth below, however, Grenfell-Gardner expressly and falsely denied the existence of a 483 Letter during the Class Period and also concealed Teligent's systematic regulatory compliance failures. In fact, as of this filing, he has still not disclosed any of the three 483 Letters.

B. Defendants' Materially False and Misleading Statements During the Class Period

92. On March 7, 2017, Teligent issued a press release announcing its Q4 2016 and FY2016 results. For Q4 2016, the Company's revenue from its topical and injectable products almost doubled as compared to Q4 2015. For FY2016, the Company: had revenue of approximately $67 million, an increase of 51% over FY2015; had a net loss of approximately $12 million, compared to net income of approximately $6.7 million the previous year; submitted 12 ANDAs to the FDA (six of which were submitted in Q4 2016); and received nine ANDA approvals from the FDA. Additionally, for FY2017, Teligent provided revenue guidance of between $85 to $100 million, a projected increase of 27% to 49% as compared to FY2016.

93. The press release also quoted Defendant Grenfell-Gardner as making the false and misleading statement that "***Teligent continued to execute and grow our business***." [Emphasis added]. Further, it quoted him touting Teligent's purported transformation and positioning for future growth, ***"[w]e are well underway with the significant expansion of our manufacturing facility located in Buena, NJ. . . . Completion of the facility expansion by the end of 2017 will allow us to plan to submit our first injectable ANDA to the FDA in the first half of 2018.***" [Emphasis added]. Similarly, the press release quoted Grenfell-Gardner stating, "***[w]e believe that we are well-positioned to increase revenue up to $85 to $100 million in 2017***," and "***we continue to invest in R&D to drive our future growth . . . [t]his investment would allow us to continue to file aggressively in the U.S. and Canada in 2017, and to advance our first organically-developed sterile injectable products***." [Emphasis added].

94. Later on March 7, 2017, Defendants held a conference call during which Grenfell-Gardner made further false and misleading statements to the public. After touting Teligent's year-over-year growth in Q4 2016 and FY2016, Grenfell-Gardner claimed "***[t]his growth continue[s] to be driven by Teligent's focus on execution through getting drugs approved, making them and launching them***." [Emphasis added]. As a result, Teligent's "***portfolio has undergone a significant change and de-risking, as we've continued to bring new products to market***." [Emphasis added].

95. He then went on to tout Teligent's pipeline:

> As of year-end 2016, our pipeline at FDA had a total addressable market for Quintiles IMS of $2 billion. ***This pipeline that Teligent has built we believe is a rather unique asset and I want to be certain that we all understand how this pipeline sets Teligent apart from much of the rest of our peer group in the generic industry.*** You may recall that I referred to Teligent as the disrupter in our industry early in 2016. What I meant by that was that ***Teligent's ability to navigate drugs through the approval process at FDA in a timely manner and launch them successfully makes us a little bit different. We're not so much***

> ***playing defense trying to protect our installed markets, but rather playing offence as we launch new drugs into the market.*** That's why if you compare our results to those of our peers, a few key differentiators stand out. First, ***we invest significantly more in R&D and we get significantly more out of it.***
>
> * * *
>
> Second, ***we punch above our weight when it comes ANDAs on file with the FDA, particularly in the specialty generic space.*** And finally, because we are market entrants rather than incumbents, we don't face the same pricing erosion that our competitors do.

[Emphasis added].

96. Similarly, Grenfell-Gardner claimed that Teligent's R&D was so robust that it would soon be able to move from its core topical products, which faced more competition, to injectable products, which could generally achieve greater returns:

> We've begun the process of transitioning our R&D focus from topicals to injectables, which will be largely complete by the fourth quarter of this year. We're able to do this as by the fourth quarter, ***we will have substantially achieved our goals around our topical development program with topical ANDAs becoming more focused on applications which require in-depth clinical endpoint studies***.

[Emphasis added].

97. He also stated that Teligent's imminent move to injectable products was a result of the Company's purported progress on updating its plant:

> We've been making great strides in the build out of our facility expansion at the manufacturing site in Buena Vista Township, New Jersey. ***We are on track to have the facility finished and validated by the end of this year, which will enable us to hit our timelines for in-house injectable ANDA submissions by the first half of 2018***.

[Emphasis added].

98. Grenfell-Gardner emphasized that Teligent's performance and positioning was based on Defendants' strong execution in developing generic products and timely ensuring their approval:

> ***[W]e're committing to continuing our extreme focus on execution. We believe in developing drugs, getting them approved, and launching them in the market, all in a timely manner.*** We believe this is the foundation of a sound specialty generic pharmaceutical business and ***we are absolutely dedicated to executing this business plan whilst continuing to manage our cost structure*** and our supply chain. ***That's what we do best at Teligent***.

[Emphasis added].

99. Further, he assured investors that Teligent's high development costs, which contributed to Teligent's net loss for FY2016 despite increased revenue, were driving the Company's growth and profitability:

> [W]e will continue to invest in R&D, as we maintain our aggressive focus on the pipeline. We anticipate the total R&D expense for the year 2017 to approximate 24% to 27% of total revenue. ***Our investment in this pipeline is what drives and will continue to drive our growth and profitability in the years to come***.

[Emphasis added].

100. In response to an analyst's comment that Teligent's six ANDA submissions in Q4 2016 were "a little bit light," and related question regarding what Teligent's "cadence" of ANDA "filings" would be in 2017, Grenfell-Gardner concealed the problems undermining the Company's ANDA pipeline and the 483 Letter it had received from the FDA in September 2016:

> ***So I think we intentionally didn't want to start thinking about numbers of filings in the year, but rather the quality of the filings and their likelihood of approval within our first cycle review. That's our focus as we think about the pipeline.***
>
> And you go back and look at the fourth quarter of 2016, I think you can see some of that. ***We actually responded to, I think the final total was something like 120 interactions with FDA related to the pipeline last year. So when you think about that workload, together with new ANDA submissions, obviously, getting stuff out of the FDA is probably more important than throwing stuff into the FDA, particularly if you don't have the time and the effort to quality check it.***
>
> ***We don't want to do that***. So the other piece of this is to be mindful that in the first half of this year, you have the overlap of the review cycle periods for GDUFA Year 4 and GDUFA Year 5. You'll know, Matt, that in GDUFA Year 5, we're moving from a 15-month clock for first cycle review to a 10-month clock.

> *So* ***that puts a lot of strain and stress on the organization and the regulatory team and all of the teams that support to make sure that we can continue to respond to FDA on time, in a complete manner and in a quality response to the information requests that they have. That's my number one priority for the first half of this year.***
>
> ***So we've staggered the ANDA filings***. There will, of course, still be ANDA filings in the first half of this year. And we'll update you on a quarterly basis as we progress. But I don't want to focus on that ANDA submission cadence. ***What I want to focus on is the quality of our responses to get drugs approved.***

[Emphasis added].

101. Additionally, in response to an analyst's question about why Teligent's competitors were recently discussing plans for injectable products and how those plans impacted Teligent, Grenfell-Gardner touted Teligent's purported regulatory expertise compared to regulatory problems that other companies were having:

> ***You look at some of the major facilities that supply the market and they continue to have ongoing regulatory challenges. We've seen warning letters even over the course of the past few weeks related to sterile injectable manufacturing sites run by some of the largest companies in the world.***
>
> So, look I think that you've got to be mindful of a couple of things. First, there is a physical plant question, where you're going to make these sterile injectable drugs. ***I will tell you that many of the facilities that exist for sterile injectable manufacturer probably need to make some pretty significant investments around the manufacturing technology that supports that and that's not an easy thing to do.***
>
> * * *
>
> We've been working on this injectable plan since 2014 when we acquired our first injectable ANDAs and NDAs. We brought the first of those drugs back to market. We've built a team, a really amazing team for injectable drug development. And we've started building the physical plant that will now be in place at the end of this year. ***That's a lot of work and a lot of process in a company that's very focused on getting stuff done. I'm not sure how in a slightly bigger or perhaps slower organization how that might happen quite to the extent that we do.***

[Emphasis added].

102. The foregoing statements in ¶¶93-101 were materially false and misleading because, at the time they were made:

(a) As described in the FDA's correspondence with Teligent in September 2016 (including the 483 Letter, EIR, and follow-up letters from Teligent and the FDA), October 2017 (including the 483 Letter, EIR, and follow-up letter from Teligent), and May 2019 (including the 483 Letter and follow-up letter from Teligent), as well as by CW1, before and during the Class Period, Teligent had a widespread failure to implement required SOPs and controls, exacerbated by a badly understaffed Quality Control department. This resulted in Teligent systematically failing to comply with FDA regulations, which undermined the integrity of the data Teligent submitted to the FDA in support of its ANDAs. Accordingly, contrary to Defendants' claims, Teligent's heavy investment in R&D would ***not*** "allow us to continue to file aggressively in the U.S. and Canada in 2017," Teligent did ***not*** have a "rather unique . . . ability to navigate drugs through the approval process at FDA in a timely manner" that "sets [it] apart from much of the rest of our peer group," Teligent's "investment in this pipeline" was ***not*** "what drives and will continue to drive our growth and profitability," and, among other claims, Teligent had ***not*** focused on the "quality of the [ANDA] filings" it made with the FDA and had, ***in fact, not*** invested the "time and the effort to quality check" them. Indeed, Teligent not only had to redo tests and studies for the faulty ANDAs it had submitted, so that they had a chance of receiving approval, but it had to implement a host of new SOPs and controls across its laboratory and related infrastructure – in response to compliance failures the FDA had specifically identified and the many others Teligent was now expressly warned to correct – to improve the quality of future ANDA submissions and rebuild its standing with the FDA. This delayed the potential approval of Teligent's already submitted ANDAs, caused the submission of its new ANDAs to slow to an almost complete halt, made the TICO strategy

impossible to implement, and resulted in a waste of Teligent's high R&D and other expenses, which the dwindling pipeline could not earn sufficient revenue to cover.

(b) Moreover, they concealed the September 2016 483 Letter, accompanying EIR, and subsequent follow-up letter from the FDA, which contained observations of multiple, systematic compliance failures in Teligent's SOPs and laboratory controls and undermined the integrity of the data that Teligent was submitting in support of its ANDAs. They concealed that information notwithstanding that their own (undisclosed) follow-up letter to the FDA in October 2016 stated that "Teligent takes these observations extremely seriously." Accordingly, contrary to Defendants' claims, and among others, such as the claims noted in sub-paragraph "(a)" immediately above, Teligent had ***not just*** "seen warning letters even over the course of the past few weeks . . . [at] some of the largest companies in the world," but had ***itself received*** the September 2016 483 Letter and related correspondence only several months earlier. As set forth above, responding to those observations and warnings required a substantial amount of Teligent's already overtaxed resources, both for the ANDAs already submitted and prospective infrastructure fixes, thereby delaying the approval of existing ANDAs, delaying the submission of new ANDAs, and limiting Teligent's ability to execute its business plan. This further showed that Teligent was already experiencing serious regulatory problems with its topical drugs, which were easier to produce than the new categories of drugs Teligent sought to expand into, and which Teligent had significantly greater expertise with, thereby undermining Defendants' claim that they were well positioned to expand into injectable drugs and the other new drug categories that had better market conditions than topicals.

(c) Also, the injectable facility was already experiencing significant delays in its development timeline, making it unlikely to support injectable products on the timeline Defendants promised. Accordingly, contrary to Defendants' claims, Teligent was ***not*** "on track to have the [sterile] facility finished and validated by the end of this year" or "to hit our timelines for in-house injectable ANDA submissions by the first half of 2018," and, among other things, the "work" Teligent had done on the sterile facility did ***not*** set Teligent apart from "bigger or slower organizations" because the facility was well behind schedule and that work had contributed to Teligent exhausting its limited resources such that it could not comply with the regulations necessary to support its core pipeline of topical ANDAs, let alone develop injectable ANDAs or the broader TICO strategy.

103. On March 13, 2017, Defendant Grenfell-Gardner spoke at the Roth Capital Conference, at which he made materially false and misleading statements to the public. He claimed that, "We've had a very successful track record with the FDA in that facility. Our last three audits over the past five years, ***there have been no 483 observations at that site***." [Emphasis added]. Similarly, he assured investors that "***our cooperation with the FDA has been incredibly fruitful and straightforward***." [Emphasis added].

104. Grenfell-Gardner also claimed that Defendants' plan to enhance the Company's facilities and develop injectable products was on track, due to its heavy investment in capital along with its development and regulatory capabilities:

> ***The facility has made some really remarkable progress over the past many weeks. And we are on track to hit our goals. So, it's really exciting. So, Phase 1 is complete. Phase 2 is under way. We're actually finishing out in our Phase 3 in terms of the water tightness of that facility. And Phase 4, so the second and third quarters of this year, we'll be transitioning and sort of moving around the various manufacturing lines to be able to continue to support the business.***
>
> So, why are we then making that move into the injectable space? During these conferences and during these conversations, we often hear about people telling us

> lots of people are looking at the injectable space; lots of people are thinking about injectables. And it's really great, ***but there are lots of people thinking about stuff. We're actually building it. So, we're dedicating the capital. We're doing the R&D. We have products on the market. We've got the development capability. And we the [sic] regulatory skills to take these products from thinking about to actually being available for patients.***

[Emphasis added].

105. At the same time, with respect to Teligent's ANDA submission pipeline, Grenfell-Gardner told investors, "***[i]f you think about the pace of the approvals that we had last year, the goal is to get as many into the FDA as we're getting out of the FDA***." [Emphasis added].

106. He also told investors how Teligent's purported ability to get ANDAs approved by the FDA, while developing and growing its pipeline of new ANDAs, impacted the Company's FY2017 guidance:

> Just to talk a little bit about the financial highlights for 2017, we've given guidance of revenue of between $85 million and $100 million for 2017. Just to say the way that we construct our guidance is to start with the low end of the range being a sort of universe of what we know. So, what have we had approved, might be pending launch, building on the last quarter of 2016. ***The upper end of that range is our expectations based on things we believe that could come out of FDA throughout the year, and we think that gives us a good starting point for the guidance for the year.***
>
> In addition, we're continuing to invest significantly in R&D. Obviously, the base of sales is where it is. So, we invest significantly more as a percentage of revenue than our peers, but we're investing now 24% to 27% for 2017. That will moderate over time as the pipeline grows; that percentage will trend towards industry norms of around 10% as you get in the out-years of the model. ***But for now, that's the best investment that we can make because the FDA is approving the drugs that we submit.***

[Emphasis added].

107. The foregoing statements in ¶¶103-06 were materially false and misleading because, at the time they were made:

(a) As described in the FDA's correspondence with Teligent in September 2016 (including the 483 Letter, EIR, and follow-up letters from Teligent and the FDA), October

2017 (including the 483 Letter, EIR, and follow-up letter from Teligent), and May 2019 (including the 483 Letter and follow-up letter from Teligent), as well as by CW1, before and during the Class Period, Teligent had a widespread failure to implement required SOPs and controls, exacerbated by a badly understaffed Quality Control department. This resulted in Teligent systematically failing to comply with FDA regulations, which undermined the integrity of the data Teligent submitted to the FDA in support of its ANDAs. Accordingly, contrary to Defendants' claims, Teligent ***in fact*** had "483 observations at [its Buena] site," Teligent's interactions with the FDA had ***not*** been "straightforward," Teligent could ***not*** meet its "goal" of "get[ting] as many [ANDAs] into the FDA as we're getting out of the FDA" because it had to focus virtually all of its resources on salvaging already-submitted ANDAs and brings its laboratory and related infrastructure into regulatory compliance, and, among other things, Teligent's heavy R&D costs were ***not*** "the best investment that we can make" because it was ***not*** true that "the FDA is approving the drugs that we submit." Indeed, Teligent not only had to redo tests and studies for the faulty ANDAs it had submitted, so that they had a chance of receiving approval, but it had to implement a host of new SOPs and controls across its laboratory and related infrastructure – in response to compliance failures the FDA had specifically identified and the many others Teligent was now expressly warned to correct – to improve the quality of future ANDA submissions and rebuild its standing with the FDA. This delayed the potential approval of Teligent's already submitted ANDAs, caused the submission of its new ANDAs to slow to an almost complete halt, made the TICO strategy impossible to implement, and resulted in a waste of Teligent's high R&D and other expenses, which the dwindling pipeline could not earn sufficient revenue to cover.

(b) Moreover, they concealed and falsely denied the existence of the September 2016 483 Letter, accompanying EIR, and subsequent follow-up letter from the FDA, which contained observations of multiple, systematic compliance failures in its SOPs and laboratory controls and undermined the integrity of the data that Teligent was submitting in support of its ANDAs. They concealed that information notwithstanding that their own (undisclosed) follow-up letter to the FDA in October 2016 stated that "Teligent takes these observations extremely seriously." Accordingly, contrary to Defendants' claims, and among others, such as the claims noted in sub-paragraph "(a)" immediately above, Teligent ***in fact*** had "483 observations at [its Buena] site," and, among other things, Teligent's interactions with the FDA had ***not*** been "straightforward." As set forth above, responding to those observations and warnings required a substantial amount of Teligent's already overtaxed resources, both for the ANDAs already submitted and prospective infrastructure fixes, thereby delaying the approval of existing ANDAs, delaying the submission of new ANDAs, and limiting Teligent's ability to execute its business plan. This further showed that Teligent was already experiencing serious regulatory problems with its topical drugs, which were easier to produce than the new categories of drugs Teligent sought to expand into and which Teligent had significantly greater expertise with, thereby undermining Defendants' claim that they were well positioned to expand into injectable drugs and the other new drug categories that had better market conditions than topicals.

(c) Also, the injectable facility was already experiencing significant delays in its development timeline, making it unlikely to support injectable products on the timeline Defendants promised. Accordingly, contrary to Defendants' claims, and among others, such as the claims noted in sub-paragraph "(a)" immediately above, Teligent was ***not*** "on

track to hit our goals" at the facility. Further, attempting to expand the facility had contributed to Teligent exhausting its limited resources such that it could not comply with the regulations necessary to support its core pipeline of topical ANDAs, let alone develop injectable ANDAs or the broader TICO strategy.

108. On March 15, 2017, Teligent filed its Form 10-K Annual Report for 2016 (the "2016 10-K"). In the "Risk Disclosures" section of the 2016 10-K, Teligent made the following false and misleading statements:

> ***We may encounter delays in testing and manufacturing new pharmaceutical products, submitting applications for regulatory approval, receiving approval from the relevant authorities and commercializing new products.***
>
> * * *
>
> ***As a manufacturer of pharmaceutical products, we must also comply with cGMPs, or current Good Manufacturing Practices, which include requirements related to production processes, quality control and assurance and recordkeeping. Our manufacturing facilities and procedures and those of our suppliers are subject to periodic inspection by the FDA and foreign regulatory agencies. Any material deviations from pharmaceutical cGMPs or other applicable requirements identified during such inspections may result in recalls or other enforcement actions, including warning letters, a delay or suspension in manufacturing operations, consent decrees or civil or criminal penalties. Further, discovery of previously unknown problems with a product or manufacturer may result in restrictions or sanctions, including suspension or withdrawal of marketing approvals, seizures or recalls of products from the market, or civil or criminal fines or penalties, any of which could significantly and adversely affect supplies of our products.***

[Emphasis added].

109. The statements in the preceding paragraph were materially false and misleading at the time they were made because:

(a) As described in the FDA's correspondence with Teligent in September 2016 (including the 483 Letter, EIR, and follow-up letters from Teligent and the FDA), October 2017 (including the 483 Letter, EIR, and follow-up letter from Teligent), and May 2019

(including the 483 Letter and follow-up letter from Teligent), as well as by CW1, before and during the Class Period, Teligent was already experiencing serious development, manufacturing, quality control, laboratory, and regulatory failures, rendering it non-compliant with cGMP "requirements related to production processes, quality control and assurance and recordkeeping." Moreover, Teligent had already received notice from the FDA of specific compliance failures, and the Company was further warned to fix any other compliance failures, of which there were many. Those failures were negatively impacting the Company's ability to develop new products, win ANDA approvals, and manufacture products. In turn, that undermined the purported value of Teligent's pipeline, success of its TICO strategy, benefits of its heavy R&D investments, and its positioning for growth and profitability.

(b) Further, they concealed the existence of the September 2016 483 Letter, accompanying EIR, and subsequent follow-up letter from the FDA, which contained observations of multiple, systematic compliance failures in Teligent's SOPs and laboratory controls and undermined the integrity of the data that Teligent was submitting in support of its ANDAs. They concealed that information notwithstanding that their own (undisclosed) follow-up letter to the FDA in October 2016 stated that "Teligent takes these observations extremely seriously." Thus, for example, the claimed hypothetical risk that Teligent "may encounter delays in . . . submitting applications for regulatory approval, receiving approval from the relevant authorities and commercializing new products" had already come to pass. As set forth above, responding to those observations and warnings required a substantial amount of Teligent's already overtaxed resources, both for the ANDAs already submitted and prospective infrastructure fixes, thereby delaying the

approval of existing ANDAs, delaying the submission of new ANDAs, and limiting Teligent's ability to execute its business plan. This further showed that Teligent was already experiencing serious regulatory problems with its topical drugs, which were easier to produce than the new categories of drugs Teligent sought to expand into and which Teligent had significantly greater expertise with, thereby undermining Defendants' claim that they were well positioned to expand into injectable drugs and the other new drug categories that had better market conditions than topicals.

(c) Also, the injectable facility was already experiencing significant delays in its development timeline, making it unlikely to support injectable products on the timeline Defendants promised. Moreover, amidst the development failures set forth in the preceding paragraphs, Teligent was already experiencing a substantial slowdown in its ANDA submissions for its core topical business, which, in turn, delayed and threatened its ability to develop and produce the more complex injectable drugs on the promised timeline.

110. Additionally, in the 2016 10-K, Teligent made the following false and misleading statement: "***We have an FDA-registered, cGMP-compliant facility that is equipped for manufacturing topical, semi-solid and liquid products***." [Emphasis added].

111. The statement in the foregoing paragraph was false and misleading because at the time it was made, Teligent's facility was ***not*** "cGMP-compliant." Rather, as set forth above, and as the three sets of correspondence with the FDA observed, Teligent had multiple breaches of cGMP during and prior to the Class Period, including a lack of appropriate method validations for its tests, failure to have and follow required SOPs, and a failure to prevent contamination.

112. On May 2, 2017, Teligent issued a press release announcing its Q1 2017 quarterly results. It stated that the Company had increased revenue over the same quarter a year ago and

sequentially, which included an increase in revenue from the products it had developed year-over-year. Two of the Company's ANDAs also received approval. Further, the Company maintained its revenue guidance of between $85 to $100 million for FY2017, with gross margins between 50% to 54%, and R&D costs between 24% to 27% of revenue.

113. Later that day, Defendants held a conference call at which Grenfell-Gardner made false and misleading statements to the public. He repeatedly claimed that Teligent's strong development, compliance, and regulatory capabilities were creating a successful pipeline of products and positioned that pipeline for growth:

> ***[O]ur team is focused on delivering products in the existing product pipeline, responding to FDA and HealthCanada inquiries and preparing for the final submissions for 2017. . . . And we are committed to upholding our responsibilities with respect to the FDA to ensure the timely processing of our applications.***

[Emphasis added].

114. Similarly, he claimed that Teligent's business was:

> ***[B]uilt on a solid product development platform, excellent regulatory capabilities and timely and effective product launch. With every quarter that passes, our fundamental commitment to this business plan diversifies our revenue base, improves our capabilities and delivers financial results.***

[Emphasis added].

115. In response to a question regarding "the current timeline, are you still on track to be able to handle injectable submissions by the first half of 2018[,]" Grenfell-Gardner answered:

> ***[Y]es. The goal, as I've said, in terms of facility expansion is to ensure that we have the facility. We're ready to produce injectable products by the end of this year, and the team has already identified the lead products that will go into that facility and what order as we get through the end of 2017 and into 2018.***

[Emphasis added].

116. Further, in response to a related question regarding the range of capabilities "on the injectables front," he stated:

> But ***the second part is around the internally developed pipeline.*** And there, what I'm particularly excited about is ***the ability of our team to start to pivot away from topical development in the back half of this year towards injectable development, and to see those teams apply the same degree of productivity towards injectables, if not better, that we had around topicals in some of our bigger topical years for the internal development program.*** . . . ***[I]t is going to be driven by a very similar philosophy around R&D productivity and getting drugs approved.***

[Emphasis added].

117. The foregoing statements in ¶¶113-16 were materially false and misleading because, at the time the statements were made:

(a) As described in the FDA's correspondence with Teligent in September 2016 (including the 483 Letter, EIR, and follow-up letters from Teligent and the FDA), October 2017 (including the 483 Letter, EIR, and follow-up letter from Teligent), and May 2019 (including the 483 Letter and follow-up letter from Teligent), as well as by CW1, before and during the Class Period, Teligent had a widespread failure to implement required SOPs and controls, exacerbated by a badly understaffed Quality Control department. This resulted in Teligent systematically failing to comply with FDA regulations, which undermined the integrity of the data Teligent submitted to the FDA in support of its ANDAs. Accordingly, contrary to Defendants' claims, Teligent was ***not*** "committed to upholding our responsibilities with respect to the FDA to ensure the timely processing of our applications," and, among other claims, Teligent did ***not*** have "excellent regulatory capabilities." Indeed, Teligent not only had to redo tests and studies for the faulty ANDAs it had submitted, so that they had a chance of receiving approval, but it had to implement a host of new SOPs and controls across its laboratory and related infrastructure – in response to compliance failures the FDA had specifically identified and the many others Teligent was now expressly warned to correct – to improve the quality of future ANDA

submissions and rebuild its standing with the FDA. This delayed the potential approval of Teligent's already submitted ANDAs, caused the submission of its new ANDAs to slow to an almost complete halt, made the TICO strategy impossible to implement, and resulted in a waste of Teligent's high R&D and other expenses, which the dwindling pipeline could not earn sufficient revenue to cover.

(b) Moreover, they concealed the September 2016 483 Letter, accompanying EIR, and subsequent follow-up letter from the FDA, which contained observations of multiple, systematic compliance failures in Teligent's SOPs and laboratory controls and undermined the integrity of the data that Teligent was submitting in support of its ANDAs. They concealed that information notwithstanding that their own (undisclosed) follow-up letter to the FDA in October 2016 stated that "Teligent takes these observations extremely seriously." Accordingly, contrary to Defendants' claims, Teligent was ***not*** "committed to upholding our responsibilities with respect to the FDA to ensure the timely processing of our applications," and, among other claims, Teligent did ***not*** have "excellent regulatory capabilities." As set forth above, responding to those observations and warnings required a substantial amount of Teligent's already overtaxed resources, both for the ANDAs already submitted and prospective infrastructure fixes, thereby delaying the approval of existing ANDAs, delaying the submission of new ANDAs, and limiting Teligent's ability to execute its business plan. This further showed that Teligent was already experiencing serious regulatory problems with its topical drugs, which were easier to produce than the new categories of drugs Teligent sought to expand into and which Teligent had significantly greater expertise with, thereby undermining Defendants' claim that they were

well positioned to expand into injectable drugs and the other new drug categories that had better market conditions than topicals.

(c) Also, the injectable facility was already experiencing significant delays in its development timeline, making it unlikely to support injectable products on the timeline Defendants promised. Accordingly, contrary to Defendants' claims, Teligent was ***not*** on track with the timeline Defendants promised, and as such, could ***not*** be "ready to produce injectable products by the end of this year," and, among other claims, Teligent did ***not*** have a base infrastructure from topicals that would allow it to "pivot" to or experience "productivity" from injectables. Indeed, Teligent's work on the facility had contributed to exhausting its limited resources, such that it could not comply with the regulations necessary to support its core pipeline of topical ANDAs, let alone develop injectable ANDAs or the broader TICO strategy.

118. On May 3, 2017, at a Deutsche Bank Health Care Conference, Defendant Grenfell-Gardner made the following false and misleading statement to the public: "If you look at the [Buena] manufacturing site, so this is the site that's under significant expansion at the moment. It had a very solid track record with [the] FDA – the audits conducted ***over the last five years, there've been no 483 observations related to the site.***" [Emphasis added].

119. The statement in the foregoing was false and misleading at the time it was made because far from having a "very solid track record" at the FDA, or having "no 483 observations related to [the Buena Facility]," Teligent had received no fewer than ***five*** 483 observations in the September 2016 483 Letter following an inspection of ***that very site***, less than ***one*** year prior to the statement. Those observations were of regulatory compliance failures that undermined the integrity of the data Teligent was submitting to the FDA in support of its ANDAs. As such,

responding to those observations and warnings required a substantial amount of Teligent's already overtaxed resources, both for the ANDAs already submitted and prospective infrastructure fixes, thereby limiting Teligent's ability to execute its business plan. This further showed that Teligent was already experiencing serious regulatory problems with its topical drugs, which were easier to produce than the new categories of drugs Teligent sought to expand into and which Teligent had significantly greater expertise with, thereby undermining Defendants' claim that they were well positioned to expand into injectable drugs and the other new drug categories that had better market conditions than topicals.

120. At the Bank of America Merrill Lynch Healthcare Conference on May 16, 2017, Defendant Grenfell-Gardner made false and misleading statements to the public. After emphasizing Teligent's pipeline of ANDA submissions and portfolio of ANDA approved products, he touted the company's purported development and production strength:

> All of this we do pretty much internally through a facility that we have in New Jersey, it's an FDA [*sic*] approved site, ***No 483 observations in the last three inspection cycles, and it's a site that we're extending pretty rapidly in order to meet the demands of both at [sic] the pipeline as well as the strategy that we've set out.***

[Emphasis added].

121. He also touted Teligent's purported ability to develop its pipeline and secure a return on its high R&D costs:

> ***[Teligent] is really an offensive play around how we grow this pipeline and how we get products approved.*** You can see that over the course of the past five years, we've really invested a lot in that pipeline compared to our peers. If you look at our run rate of investment in R&D, we're at somewhere north of 20% in most years, this year somewhere between 27% and 30% I think, for the year, or 24% and 27% for the year, and last year almost 27% as well. ***That's a significant investment compared to industry, right. I mean, you look at an industry that's been investing 6%, 7%, 8% of revenue in R&D and have pipelines that look pretty anemic compared to many of our much larger brothers and sisters in this industry, Teligent has a very robust pipeline focused on the specialty area.***

* * *

> ***And finally, you look at the productivity of what we do in R&D. While so many people have been disinvesting in R&D, Teligent has kind of shifted it into another gear. And if you look at the ability of this team to file 10, 12, 15 ANDAs a year and to process the amount of FDA correspondence that comes from that successfully and in a timely manner, I think, we've done a really great job.***

[Emphasis added].

122. Grenfell-Gardner followed-on, claiming that Teligent was, in fact, successfully growing and expanding its pipeline into new and ever more complex products:

> ***What Teligent has done in terms of strategy around that portfolio is to say we will be in every AT-rated product [topicals] and every AB-rated corticosteroid [includes topicals, pills, and injections] by the end of 2017, we will have filed those products, and we are on track now to meet that goal.***
>
> * * *
>
> ***In terms of timing, we intend to fill the first liquid injectable product in this site before the end of this year. We are taking effective use of this site from September of this year, it will be substantially complete in October.***
>
> * * *
>
> ***[I]f you think about what we've been able to do in topicals and R&D by presenting 10, 12, 15 ANDAs a year to the FDA, the goal is***, as we get into 2018 and add our second and our next two development teams, taking the total number of development teams to six, is that ***we should be in a position to file somewhere around my goal of 20 ANDAs a year in injectables. I don't see anybody doing that and I know that this team is going to be able to make that happen in this site.***

[Emphasis added].

123. Moreover, he claimed that Teligent was doing all of that while meeting high regulatory and quality control standards:

> ***If you look at a number of the folks in our space, you hear a lot of complaining about FDA, you hear challenges of getting drugs approved. We don't make those complaints, we don't have those challenges. . . . [P]art of this is about the responsiveness of the team that we have. I think last year, the count was that we had something like a 130-ish inbound increase from FDA, all of which required either 7-day or 30-day response times. We responded to FDA in all of those cases on time.*** And when we talk to our peers in our industry, they say to us, why

> are you doing this? This is crazy, like nobody does that. But the reason we do it is ***because that's what it takes to get drugs approved on your GDUFA goal date***.
>
> * * *
>
> I think I started with what Steve was saying about being - playing offense, right. ***We don't worry so much about price erosion, perhaps we're the source of some people's price erosion, because we're launching products and we're bringing them to market. We're doing that very effectively and we're achieving the market shares that we set out as we bring those products to the market. It's supported by our pipeline, a pipeline that's been incredibly productive over the past couple of years and which we think will continue to drive the business as we move forward into these further product forms. It's supported by products that we make ourselves. This is not just call somebody up and have them make something and hope that their regulatory and quality systems will work. We take that responsibility very firmly in our hands, and it's driven by our people. And we've got about 160 people now between New Jersey, Toronto, Estonia that help to support this business. It's a remarkable group of people who are frankly I think the best in this industry.***

[Emphasis added].

124. The PowerPoint presentation accompanying Grenfell-Gardner's speech reiterated that Teligent purportedly had a ***"[t]rack record of successful FDA audits***," with "***[t]hree audits conducted over the past 5 years (last audit in January 2016) with no 483 observations***." [Emphasis added]. It separately stated that its facility had "***No 483 observations in the last three cGMP inspections***." [Emphasis added]. It further stated that its facility was "***cGMP-compliant***." [Emphasis added]. The presentation also emphasized the Company's purported "***[b]road Scope of Organic R&D Opportunities***," including "***to file approximately 14 more ANDAs for all commercially reasonable AT-rated products and AB-rated corticosteroids***," and also "***[d]evelopment program to expand to topical products requiring clinical end point studies. First two development programs have commenced***." [Emphasis added].

125. The foregoing statements in ¶¶120-24 were materially false and misleading because, at the time they were made:

(a) As described in the FDA's correspondence with Teligent in September 2016 (including the 483 Letter, EIR, and follow-up letters from Teligent and the FDA), October 2017 (including the 483 Letter, EIR, and follow-up letter from Teligent), and May 2019 (including the 483 Letter and follow-up letter from Teligent), as well as by CW1, before and during the Class Period, Teligent had a widespread failure to implement required SOPs and controls, exacerbated by a badly understaffed Quality Control department. This resulted in Teligent systematically failing to comply with FDA regulations, which undermined the integrity of the data Teligent submitted to the FDA in support of its ANDAs. Accordingly, contrary to Defendants' claims, Teligent ***in fact*** had "483 observations" at its Buena Facility over the last six months, Teligent was ***not*** "an offensive play around how we grow this pipeline and how we get products approved" because it was not positioned to do either, Teligent did ***not*** have the "ability . . . to file 10, 12, 15 ANDAs a year" or "to process the amount of FDA correspondence that comes from that successfully and in a timely manner," while still complying with FDA regulations, Teligent ***in fact*** had "challenges" with the FDA given the serious 483 observations, Teligent's purported plan to file "approximately 14 more ANDAs" was illusory because Teligent did not have the resources to do so, while addressing its many compliance failures, and, among other claims, Teligent's Buena Facility was ***not*** "cGMP compliant." Indeed, Teligent not only had to redo tests and studies for the faulty ANDAs it had submitted, so that they had a chance of receiving approval, but it had to implement a host of new SOPs and controls across its laboratory and related infrastructure – in response to compliance failures the FDA had specifically identified and the many others Teligent was now expressly warned to correct – to improve the quality of future ANDA submissions and rebuild its standing with

the FDA. This delayed the potential approval of Teligent's already submitted ANDAs, caused the submission of its new ANDAs to slow to an almost complete halt, made the TICO strategy impossible to implement, and resulted in a waste of Teligent's high R&D and other expenses, which the dwindling pipeline could not earn sufficient revenue to cover.

(b) Moreover, they concealed the September 2016 483 Letter, accompanying EIR, and subsequent follow-up letter from the FDA, which contained observations of multiple, systematic compliance failures in Teligent's SOPs and laboratory controls and undermined the integrity of the data that Teligent was submitting in support of its ANDAs. They concealed that information notwithstanding that their own (undisclosed) follow-up letter to the FDA in October 2016 stated that "Teligent takes these observations extremely seriously." Accordingly, contrary to Defendants' claims, and among others, such as the claims noted in sub-paragraph "(a)" immediately above, Teligent ***in fact*** had "483 observations" at its Buena site over the last six months and, as such, ***in fact*** had "challenges" with the FDA. As set forth above, responding to those observations and warnings required a substantial amount of Teligent's already overtaxed resources, both for the ANDAs already submitted and prospective infrastructure fixes, thereby delaying the approval of existing ANDAs, delaying the submission of new ANDAs, and limiting Teligent's ability to execute its business plan. This further showed that Teligent was already experiencing serious regulatory problems with its topical drugs, which were easier to produce than the new categories of drugs Teligent sought to expand into and which Teligent had significantly greater expertise with, thereby undermining Defendants' claim

that they were well positioned to expand into injectable drugs and the other new drug categories that had better market conditions than topicals.

(c) Also, the injectable facility was already experiencing significant delays in its development timeline, making it unlikely to support injectable products on the timeline Defendants promised. Accordingly, contrary to Defendants' claims, Teligent was ***not*** on track with the timeline Defendants promised and, as such, could ***not*** be "ready to produce injectable products by the end of this year," and, among other claims, Teligent did ***not*** have a base infrastructure from topicals that would allow it to "pivot" to or experience "productivity" from injectables. Indeed, Teligent's work on the facility had contributed to exhausting its limited resources, such that it could not comply with the regulations necessary to support its core pipeline of topical ANDAs, let alone develop injectable ANDAs or the broader TICO strategy.

126. On May 10 and August 9, 2017, Teligent filed its Form 10-Qs for Q1 and Q2 2017, respectively, incorporating by reference the risk disclosures in the 2016 10-K, which were materially false and misleading for the same reasons as stated with respect to the 2016 10-K, set forth in ¶¶108 & 111, *supra*.

127. On August 8, 2017, Teligent issued a press release announcing its quarterly results for Q2 2017. Teligent reported an increase in total revenue and in revenue from products it developed, as compared to the same quarter in the previous year, and also a decrease in gross margins on a year-over-year (and sequential) basis. With respect to ANDAs, it did not report any approvals by the FDA during the quarter and reported submitting two ANDAs to the FDA. As for FY2017, Teligent dropped its revenue guidance to between $75 million and $85 million (it had

previously been between $85 million and $100 million) and dropped its gross margin guidance to between 47% and 50% (it had previously been between 50% and 54%).

128. During a conference call held later day, Defendant Grenfell-Gardner made false and misleading statements to the public. He asserted that "***[s]everal of our pending ANDAs have been impacted by regulatory inspections at 3 of our API [Active Pharmaceutical Ingredient] suppliers, infecting 8 molecules in 21 ANDAs***, representing $745 million of our pipeline's total addressable market, or 37%." [Emphasis added]. (Note: these were inspectors at Teligent's *suppliers*, not at Teligent's own facility). Specifically, ***those suppliers received "483 observations"*** from the FDA. [Emphasis added]. Although several of those observations had recently been cleared, that situation purportedly "***delayed***" the approval time of the "***impacted***" Teligent ANDAs and, along with changed market conditions for one approved product, "***caused us to update our guidance for the year***." [Emphasis added].

129. Grenfell-Gardner then assured investors, "***Looking ahead to coming months, we have reviewed the applications pending with the FDA and believe that there are approximately 10 potential approvals that we could anticipate before the end of the year with the total addressable market of $345 million***."

130. Additionally, in response to an analyst question regarding Teligent's implementation of the TICO strategy, and how that strategy impacted the Company's ability to withstand changes in the business cycle, Grenfell-Gardner touted the Company's development capabilities and R&D investment, along with its ANDA pipeline and ability to get ANDAs approved by the FDA:

> One of the challenges I think for all of us in this industry, whether we're are [*sic*] investors, analysts or management is to be mindful of the good things when they happen, but not expect them to last forever, right. The sole source position in a Zantac or in a Lidocaine or anything is a passing event. And it's a great thing and

> you take advantage of it while you can and you make sure that you manage your supply chain to be able to have that advantage. ***But underneath all of that, you have to be building a business that has a robust R&D pipeline. The ability to get drugs approved. And the diversification that allows you to have a portfolio approach to that market. And I think that's what we have done in the topical piece. And you translate that to what's going on in injectables.*** In injectables we still see significant market disruption on a regular basis. That's what put us in this position with Zantac, it's put us from time to time in positions with some of the cephaelis forms. We look at Canada, and in Canada we're often in sole source positions because of supply-chain issues. ***Again, those will come and go, what increases your optionality is the pipeline that supports it. And we continue to do our work in the complex side. We continue to do our work on ophthalmics.*** So I think coming back to your question, are we hitting towards the bottom of this or not? I don't know. I don't know because it's all going to depend on what happens in individual products and supply chains over the course of the coming weeks and months. ***What we do know is that FDA is being significantly more responsive. It is working through applications more quickly. And so for those of us who are in markets where we've developed these pipelines and these capabilities, I think we should benefit as they continue to get approved.***

[Emphasis added].

131. The foregoing statements in ¶¶128-30 were materially false and misleading because, at the time they were made:

(a) As described in the FDA's correspondence with Teligent in September 2016 (including the 483 Letter, EIR, and follow-up letters from Teligent and the FDA), October 2017 (including the 483 Letter, EIR, and follow-up letter from Teligent), and May 2019 (including the 483 Letter and follow-up letter from Teligent), as well as by CW1, before and during the Class Period, Teligent had a widespread failure to implement required SOPs and controls, exacerbated by a badly understaffed Quality Control department. This resulted in Teligent systematically failing to comply with FDA regulations, which undermined the integrity of the data Teligent submitted to the FDA in support of its ANDAs. Accordingly, contrary to Defendants' claims, the delay in Teligent's ANDA approvals was ***not*** simply a result of FDA inspections at its "suppliers," but rather involved Teligent's ***own*** compliance failures, as identified by the FDA, and as a result of Teligent's

compliance failures, Defendants had ***no basis*** to "anticipate before the end of the year" approximately "10 potential [ANDA] approvals," for its compliance failures meant that Teligent did ***not*** have the "ability to get drugs approved," and, among other claims, Teligent, therefore, was ***not*** positioned to "benefit as [ANDAs] continue to get approved" by the FDA. Indeed, Teligent not only had to redo tests and studies for the faulty ANDAs it had submitted, so that they had a chance of receiving approval, but it had to implement a host of new SOPs and controls across its laboratory and related infrastructure – in response to compliance failures the FDA had specifically identified and the many others Teligent was now expressly warned to correct – to improve the quality of future ANDA submissions and rebuild its standing with the FDA. This delayed the potential approval of Teligent's already submitted ANDAs, caused the submission of its new ANDAs to slow to an almost complete halt, made the TICO strategy impossible to implement, and resulted in a waste of Teligent's high R&D and other expenses, which the dwindling pipeline could not earn sufficient revenue to cover.

(b) Moreover, they concealed the September 2016 483 Letter, accompanying EIR, and subsequent follow-up letter from the FDA, which contained observations of multiple, systematic compliance failures in Teligent's SOPs and laboratory controls and undermined the integrity of the data that Teligent was submitting in support of its ANDAs. They concealed that information notwithstanding that their own (undisclosed) follow-up letter to the FDA in October 2016 stated that "Teligent takes these observations extremely seriously." Accordingly, contrary to Defendants' claims, and among others, such as the claims noted in sub-paragraph "(a)" immediately above, it was ***not*** just Teligent's suppliers that had "483 observations," but Teligent itself recently had them as well. As set forth

above, responding to those observations and warnings required a substantial amount of Teligent's already overtaxed resources, both for the ANDAs already submitted and prospective infrastructure fixes, thereby delaying the approval of existing ANDAs, delaying the submission of new ANDAs, and limiting Teligent's ability to execute its business plan. This further showed that Teligent was already experiencing serious regulatory problems with its topical drugs, which were easier to produce than the new categories of drugs Teligent sought to expand into and which Teligent had significantly greater expertise with, thereby undermining Defendants' claim that they were well positioned to expand into injectable drugs and the other new drug categories that had better market conditions than topicals.

(c) Also, the injectable facility was already experiencing significant delays in its development timeline, making it unlikely to support injectable products on the timeline Defendants promised. Accordingly, contrary to Defendants' claims, Teligent did ***not*** have a base infrastructure from topicals that would allow it to "translate" any productivity to injectables. Indeed, Teligent's work on the facility had contributed to exhausting its limited resources such that it could not comply with the regulations necessary to support its core pipeline of topical ANDAs, let alone develop injectable ANDAs or the broader TICO strategy.

C. The Truth Emerges: Corrective Disclosure and Post-Class Period Events

132. On November 6, 2017, Teligent issued a press release after the market closed announcing its results for Q3 2017. It reported $13.7 million in revenue, a 15% decrease compared to the same quarter a year ago, and a sequential decrease as well. Of that, $11.8 million was from sales of Teligent's own products, also a 15% decrease compared to the same quarter a year ago, and another sequential decrease. Gross margin dropped to 24%, down almost 50% from the same

quarter a year ago, and almost as much sequentially. Through the first three quarters of 2017, the Company had total revenue of approximately $45.4 million, compared to R&D expenses of $13.4 million, and a net loss of just over $9 million. Accordingly, that quarter Teligent suffered a net loss of $8.9 million, which was substantially worse than the $2.7 million in net loss Teligent experienced the same quarter a year earlier.

133. With respect to ANDAs, through the first three quarters of 2017, the Company received five approvals from the FDA (it also had one in partnership with another company) and reported filing two new submissions with the FDA.

134. For the second quarter in a row, Teligent reduced its FY2017 revenue guidance, this time to between $65 million and $67 million (down approximately 33% from its original forecast and down approximately 13% to 21% from the initial reduction); and also reduced its FY2017 gross margin guidance to 38% to 40% (down approximately 26% to from its original forecast and down approximately 19% to 20% from the initial reduction).

135. The press release quoted Grenfell-Gardner as stating, "***[t]hese results and our revised outlook for the remainder of the year, are a result of the knock-on effect of ANDA approval delays***," as well as decreased performance for one approved product. [Emphasis added].

136. On a conference call held later that day, Defendants made additional corrective disclosures to the public. In response to a question about how much of the latest reduction in the FY2017 revenue guidance was attributable to pipeline delays, Grenfell-Gardner stated:

> ***It's really almost entirely driven by pipeline delays***. I mean, there were expectations that we had of products that we believe were ripe for approval, that we have been pre-staging materials and inventory for, but then you'd come up with another sort of question and another cycle of review. ***That's the biggest impact to us in terms of the forecast***.

[Emphasis added].

137. Similarly, in response to an analyst's question regarding Teligent's 10 ANDA submissions that Grenfell-Gardner had previously said could be approved by the end of the year (during the August 6, 2017, conference call), he expressed doubt as to whether so many would be approved in that time frame, stating now that there was only "***potential for another couple of approvals throughout the rest of this year***." [Emphasis added]. He also walked-back the claim that the hold-up of those approvals related to problems at the ***supplier's*** manufacturing sites. Thus he stated, ***"[o]f those 10, I mean, certainly there are 4 there where I see minor complete response letters that really were often related to the [supplier's] sites that we talked about earlier or other sort of minor issues***." [Emphasis added].

138. Also, while Grenfell-Gardner attributed Teligent's low Q3 2017 revenue primarily to price erosion in the performance of a single approved product that "was not entirely unexpected," he admitted that Teligent's pipeline was not able to sufficiently mitigate that situation because "***new launches do take time to ramp up***." [Emphasis added].

139. He also disclosed that "***our team faced manufacturing challenges***." [Emphasis added]. They included "an excipient in a high-volume product that was being provided to us with particles that had the potential to adulterate our finished goods" – an apparent reference to the contaminated product reported by the FDA in the October 2017 483 Letter, although he did not expressly discuss that 483 Letter or the September 2016 483 Letter during the conference call. He explained that "the team spent a significant amount of effort in resolving these challenges." As a result, "the engineering expenses related to the fix contributed to lower-than-anticipated margins in the quarter."

140. As for Teligent's ability to produce its own injectable products to diversify into the more attractive lines of the TICO strategy, Grenfell-Gardner explained that this was far off, with

the schedule becoming more oblique and distant than his earlier firm pronouncements – such as having the facility "validated" by the end of 2017 and in-house injectable ANDA submissions within the first half of 2018 (which he had stated on March 7, 2017). Now, Teligent simply had a "***goal[s]***" of "***produc[ing] the first lots to support pre-approval inspection in the second quarter [of 2018]***" and "***hav[ing] product available in the market by the fourth quarter of 2018.***" [Emphasis added]. Moreover, it was not clear how that latter goal for product availability was possible given the late timing of the former goal regarding the first lots to support pre-approval.

141. Other figures Teligent revealed in the press release and during the conference call indicated that Teligent's vaunted pipeline had sharply declined compared to the previous year. Through the first nine months of 2017, Teligent had only submitted two ANDAs with the FDA, far below the eight ANDAs it had submitted in the first nine months of 2015 and the six ANDAs it had submitted in the first nine months of 2016. (Teligent went on to submit only a total of four ANDAs in FY2017, compared to 15 ANDAs in FY2015, and 12 in FY2016).

142. Further, through the first nine months of 2017, Teligent had only received five ANDA approvals from the FDA, with a collective TAM (total addressable market) of $87.1 million. (Teligent would only have a total of eight ANDAs approved in 2017 through its internal pipeline, with an approximate TAM of $150.6 million (and also one approval of a partnered application), compared to nine ANDA approvals in FY2016 with a collective TAM of $1.64 billion).

143. Teligent was not meeting its goal of replacing ANDA approvals with ANDA submissions, so its overall ANDA pipeline was shrinking. Further, Teligent had still not submitted with the FDA any ANDA that it had developed on its own for any product outside of the topical category, despite its vaunted TICO strategy.

144. As a result of these disclosures of the pipeline delays, manufacturing problems, and their impact on Teligent's performance and guidance, on the next trading day, November 7, 2017, the price of Teligent common stock dropped 43.62%, from $5.25 per share to $2.96 per share, on a volume of 8.35 million shares.

145. Due to its deeply entrenched compliance failures and the related FDA investigations, Teligent's poor performance persisted well after the end of the Class Period. In FY2018, it submitted only three ANDAs with the FDA, even fewer than in 2017. Accordingly, though Teligent's ANDA approvals did increase somewhat from 2017, the Company's overall ANDA pipeline continued to decline sharply over the course of 2018. By the end of 2018, the Company had still only managed to submit one ANDA with the FDA that it had developed on its own for any product outside of the topical category, despite its vaunted TICO strategy, and still none for injectable drugs (that one ANDA was for a complex generic, part of the 'C' in the TICO strategy). As such, for FY2018, the Company's revenue was close to flat with the disappointing FY2017 numbers, while its net loss more than doubled compared to FY2017 and its R&D costs remained approximately 20% of its revenue. In 2019, Teligent has so far not announced any new ANDA submissions. Meanwhile, its 2019 revenue and net losses are so far on track to be essentially flat with 2018; and in the spring of 2019, Teligent received yet another 483 Letter from the FDA. Though Teligent has had several ANDA approvals in 2018 and 2019, as the foregoing performance figures show, they were insufficient to make up for the shrinking pipeline of new ANDAs to improve Teligent's revenue or to stem its steep net losses.

146. Currently, Teligent's stock price is just $0.61, and it has been trading below $1.00 for several months, placing it in violation of the Nasdaq's rules that generally require publicly traded companies that trade on the Nasdaq to trade above that amount. If a company's common

stock remains below $1.00 for 30 consecutive days, the Nasdaq puts the stock on a list of "Non-Compliant Companies" and requires them to take steps to come back into compliance within 180 days or face de-listing from the Global Select Market. Compliance can be achieved by elevating the common stock price above $1.00 for at least 10 consecutive days. Here, on June 5, 2019, Teligent was informed by the Nasdaq that because the Company's common stock traded below $1.00 for 30 consecutive days, Teligent no longer complied with the Nasdaq's "Continued Listing Standards" and was placed on the "Non-Compliant Companies" list. After failing to raise their stock price above $1.00 for 10 consecutive days in the 180-day window, Teligent requested another 180-day extension to come into compliance with the Nasdaq's rules, but as of the date of the filing of this SAC, the Nasdaq has yet to grant the extension request.

D. Additional Scienter Allegations

147. Plaintiff repeats and realleges each and every allegation set forth above as if fully set forth herein.

148. Teligent's correspondence with the FDA makes it 100% clear that Grenfell-Gardner knew of the 483 Letters, Teligent's compliance failures observed therein, and the burdensome efforts Teligent promised to undertake in response thereto. For example, and as set forth above: the September 2016 EIR elaborating on Teligent's compliance failure notes that all FDA correspondence with Teligent is to be addressed to "Mr. Jason Grenfell-Gardner," and the FDA's February 2017 follow-up letter (in response to Teligent's remediation plan) emphasizing those failures is addressed to him as well. Substantially similar statements were made in FDA correspondence following its second and third inspections during and after the Class Period. Grenfell-Gardner and/or his direct reports also participated in all three of the inspections.

149. In addition, as Defendant Grenfell-Gardner said of Teligent, on March 13, 2017, "[w]e're 152 people, we're a small management team[.]"

150. The administrative offices where Grenfell-Gardner has his work address, 105 Lincoln Avenue in Buena, New Jersey, are part of the same complex where Teligent develops and produces its drugs, which the FDA inspected as the basis of its 483 Letters, and that the Company was failing to expand.

151. Grenfell-Gardener's biography on the Company website states that he is "leading [Teligent's] transformation into an R&D-centered pharmaceutical company." He has served as CEO since 2012 and lead Teligent's strategy to invest heavily in R&D and build up an ANDA pipeline, which he presented to investors as the engine for Teligent's growth.

152. Not only was the TICO strategy lead by Grenfell-Gardner, but developing generic products, having them approved by the FDA, and having facilities that could produce those products was Teligent's primary aim.

153. Also, Grenfell-Gardner's direct reports – in this small company – were personally responsible for development, manufacturing, and quality control. For instance, the October 2017 EIR stated that Defendant Grenfell-Gardner "has direct reports from ***Quality, Manufacturing***, Finance, Business Development, and Corporate Counsel." [Emphasis added]. Among others, the October 2017 EIR stated that Woelfel, General Manager/Plant Manager, and Lani, Senior Vice President of Quality, both reported directly to Defendant Grenfell-Gardner. Woelfel was personally issued the October 2017 483 Letter and had "direct reports from Supply Chain, Technical Services, Training, Sterile and Topical Production." Lani had "direct reports from Quality Control, Quality Assurance and Compliance."

154. Furthermore, as head of Teligent's management, Defendant Grenfell-Gardner had "the ultimate responsibility to ensure an effective pharmaceutical quality system [was] in place" and was responsible for "[p]articipat[ing] in the design, implementation, monitoring, and

maintenance of an effective pharmaceutical quality system" and "[c]onduct[ing] management reviews of process performance and product quality and of the pharmaceutical quality system." *See* CDER and CBER, *Guidance for Industry: Q10 Pharmaceutical Quality System*, U.S. DEP'T OF HEALTH & HUMAN SERVS. FOOD & DRUG ADMIN. (Apr. 2009), https://www.fda.gov/media/71553/download. He was also responsible for ensuring that NCRs were tracked, and as reflected in the FDA correspondence, Teligent did indeed track them, along with its investigations into OOS results and other deviations. *See*, *e.g.*, 21 C.F.R. §211.100(b).

155. Moreover, CW1 stated that there was pressure to submit ANDAs as quickly as possible – including by cutting corners, such as "closing" investigations prematurely – and that CW1 experienced such pressure ***directly*** from Grenfell-Gardner's direct-reports Lani and Woelfel.

156. Thus, Grenfell-Gardner was notified by the FDA, was obligated to and did track, and caused the serious flaws in Teligent's development and production operations prior to and throughout the Class Period.

157. For all of the foregoing reasons, Grenfell-Gardner knew of the serious problems that plagued Teligent's development and production attempts, and its TICO strategy, prior to and throughout the Class Period.

158. For all of the foregoing reasons, Grenfell-Gardner also knew of the significant delays in Teligent's expansion of its development and production facility, including the injectable capabilities. In addition, after making the statement set forth above in which he described Teligent's "small management team," Grenfell-Gardner went on to state that Teligent specifically designed the facility expansion so that management could oversee it, stating, with respect to that expansion:

> I think if you go after some of these things aggressively and you don't have the ability to integrate them well and to manage them, you're going to put your base

> business at risk. That wasn't something that we wanted to do. So we chose to do this stepwise somewhat slower rather than big bang development.

Further, Grenfell-Gardner had experience with similar projects, and at his prior job, had led the acquisition of a sterile injectable facility for West-Ward Pharmaceuticals. He also repeatedly published updates, including on his Twitter account, regarding the expansion work being done at the facility.

E. Loss Causation

159. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic losses suffered by Plaintiff and members of the Class (defined herein). During the Class Period, Plaintiff and Class members purchased Teligent common stock at artificially inflated prices caused by Defendants' misconduct. The price of the Company's common stock declined significantly when the substantial problems and risks misrepresented and concealed by Defendants were disclosed and Defendants' material misrepresentations and omissions were revealed to the market, causing investors' losses.

160. Before the end of the Class Period, on November 6, 2017, investors had been unaware of the following material facts about Teligent that were known to Defendants throughout the Class Period:

(a) As explained in the three 483 Letters, and confirmed by CW1, Teligent was already experiencing serious regulatory failures with respect to its development, laboratory, manufacturing, and quality control processes. These failures were reflected in the quality of Teligent's rushed, shoddy ANDA submissions. Teligent had to divert significant resources to fixing the deficiencies in its ANDAs pending with the FDA in order to have a chance of those ANDAs receiving approval, and also to implementing new and more robust SOPs and controls. But this delayed potential approval, as Teligent had to

redo flawed tests and studies, and diverted Teligent's resources from developing new ANDAs for submission. As a result, Teligent's new ANDA submissions and ANDA pipeline significantly decreased. The concealed problems with the pipeline thus undermined the foundations of Teligent's large R&D investments and TICO strategy, and as such, Teligent's positioning for growth and profitability.

(b) Teligent had received the September 2016 483 Letter prior to the start of the Class Period, and had received the October 2017 483 Letter before the end of it. While Teligent was touting its superior ability to submit ANDAs to the FDA, and have those ANDAs approved, Defendants had, in fact, received notice from the FDA that Teligent's practices were not in compliance with required regulations. That constituted a significant obstacle to ANDA approval and required burdensome commitment of resources to address, thus slowing ANDA approvals, diverting Teligent's resources from ANDA submissions, and causing the pipeline to stagnate, as described above. Furthermore, the September 2016 and October 2017 483 Letters illustrate that Teligent was already experiencing serious regulatory problems with its ***topical*** drugs, which were easier to produce and with which Teligent had more expertise than the injectable, complex, and ophthalmic drugs Teligent was seeking to expand into. The concealed September 2016 and October 2017 483 Letters showed that Teligent's claim of being well-positioned to expand into injectable, complex, and ophthalmic drugs was baseless.

(c) Teligent's injectable facility was already experiencing significant delays in its development timeline, making it unlikely to support injectable products on the timeline Defendants promised, with commercialization purportedly beginning in 2018. Moreover, as set forth above, Teligent was already experiencing a substantial slowdown in its ANDA

submissions for its core topical business, which, in turn, delayed and threatened its ability to develop and produce the more complex injectable drugs on the promised timeline.

161. Defendants' misrepresentations and omissions and fraudulent scheme, as alleged in §IV, *supra*, concealed the true adverse material facts from the market during the Class Period, leading investors to wrongly believe that Teligent was: complying with the stringent FDA regulations; at the same time capable of producing and was, in fact, producing a valuable pipeline of ANDA submissions, which would yield approved ANDAs that would become lucrative products; capable of executing its TICO strategy; nearing the ability to produce injectable drugs; and poised for growth and a return on its heavy investment in R&D and the facility expansion.

162. As alleged in §IV, *supra*, these material facts were revealed to investors for the first time on November 6, 2017. On that date, Defendants disclosed "pipeline delays" and reduced revenue guidance resulting from products not being "ripe for approval." Defendants further disclosed that there would be fewer approvals forthcoming in 2017 than previously anticipated and admitted that Teligent's pipeline could not contribute to revenues sufficiently to make up for price erosion. Defendants also disclosed "manufacturing challenges" and acknowledged further delays in its plan to expand into injectables. Defendant Grenfell-Gardner stated, while explaining the guidance reduction also announced that day, that "***[i]t's really almost entirely driven by pipeline delays. . . . That's the biggest impact to us in terms of the forecast.***" [Emphasis added]. He was also quoted in Teligent's press release, saying that "***[t]hese results and our revised outlook for the remainder of the year, are a result of the knock-on effect of ANDA approval delays***" (as well as decreased performance for one approved product). [Emphasis added].

163. Additionally, these pipeline and manufacturing problems, which investors learned of for the first time on November 6, 2017, were the precise and foreseeable consequences of

Teligent's regulatory compliance failures, as set forth above. Specifically, Teligent had widespread compliance failures during and before the Class Period, and prior to the Class Period, the FDA had identified multiple such failures and warned Teligent to correct them, as well as any others. Also, prior to the Class Period, Teligent committed to doing so by redoing a number of tests and studies for ANDAs it had already submitted and adding a number of SOPs and controls to its inadequate laboratory and production infrastructure. Teligent further acknowledged to the FDA that these would be time-consuming undertakings. For a small company, with limited resources and staff, this commitment, which it had to try to satisfy if it hoped to win any ANDA approvals, prevented it from also making new ANDA submissions and growing its pipeline.

164. Following the November 6, 2017, disclosures and events, as set forth in the preceding paragraphs and in §IV, which were made after trading hours on that date, the market reacted swiftly and negatively. As a result thereof, on the next trading day, November 7, 2017, the price of Teligent common stock dropped 43.62%, from $5.25 per share to $2.96 per share, on a volume of 8.35 million shares.

165. The timing and magnitude of that precipitous decline in Teligent's stock price, following the corrective disclosures described above, negates any inference that the loss suffered by investors was caused by changed market conditions, macroeconomic or industry factors, or other facts unrelated to Defendants' fraudulent conduct. Defendants' false and misleading statements, as set forth above, proximately caused foreseeable losses to investors.

V. CLASS ACTION ALLEGATIONS

166. Plaintiff brings this action as a class action, pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3), on behalf of a class consisting of all persons and entities that purchased, or otherwise acquired, the securities of Teligent during the Class Period (March 7, 2017 to November 6, 2017, inclusive), seeking to pursue remedies under the Exchange Act (the "Class"). Excluded from the

Class are Defendants; the officers and directors of the Company, at all relevant times; members of their immediate families and their legal representatives, heirs, successors, or assigns; and any entity in which any of the Defendants have, or had, a controlling interest.

167. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Teligent common stock was actively traded on the Nasdaq. While the exact number of Class members is unknown to Plaintiff at this time, and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Millions of Teligent shares were traded publicly during the Class Period on the Nasdaq. Record owners and other members of the Class may be identified from records maintained by Teligent or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

168. Plaintiff's claims are typical of the claims of Class members, who were all similarly affected by Defendants' wrongful conduct in violation of federal securities laws, which is complained of herein. Further, Plaintiff will fairly and adequately protect the interests of Class members and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

169. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' conduct alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted or misrepresented material facts about the business, operations, and prospects of Teligent; and

(c) to what extent Class members have sustained damages, and the proper measure of damages.

170. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy, since joinder of all members is impracticable. Further, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for Class members to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

VI. APPLICABILITY OF THE FRAUD-ON-THE-MARKET AND *AFFILIATED UTE* PRESUMPTIONS OF RELIANCE

171. The market for Teligent common stock was open, well developed, and efficient at all relevant times. As a result of Defendants' materially false or misleading statements and material omissions, the Company's common stock traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired the Company's common stock, relying on the integrity of the market price of such securities and on publicly available market information relating to Teligent. Plaintiff and Class members have been damaged thereby.

172. During the Class Period, the artificial inflation of the value of Teligent common stock was caused by the material misrepresentations and omissions alleged in this Complaint, thereby causing the damages sustained by Plaintiff and other Class members. As alleged herein, during the Class Period, Defendants made, or caused to be made, a series of materially false or misleading statements about the Company's business, prospects, and operations, causing the price

of the Company's common stock to be artificially inflated at all relevant times. When the truth was disclosed, it drove down the value of the Company's common stock, causing Plaintiff and other Class members that had purchased the securities at artificially inflated prices to be damaged as a result.

173. At all relevant times, the market for Teligent common stock was efficient for the following reasons, among others:

(a) Teligent stock met the requirements for listing and it was listed and actively traded on the Nasdaq, a highly efficient and automated market;

(b) As a regulated issuer, Teligent filed periodic public reports with the SEC and/or the Nasdaq;

(c) Teligent regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Teligent was followed by securities analysts employed by brokerage firms, who wrote reports about the Company, which reports were distributed to the sales force and certain customers of their respective brokerage firms and were made publicly available.

174. Based on the foregoing, during the Class Period, the market for Teligent common stock promptly digested information regarding the Company from all publicly available sources and impounded such information into the price of Teligent stock. Under these circumstances, the market for Teligent common stock was efficient during the Class Period and, therefore, investors'

purchases of Teligent common stock at artificially inflated market prices give rise to a Class-wide presumption of reliance under the fraud-on-the-market doctrine.

175. In the alternative, the *Affiliated Ute* presumption of reliance applies to the extent that Defendants' statements during the Class Period involved omissions of material facts, which concealed that:

(a) As described in the FDA's correspondence with Teligent in September 2016, October 2017, and May 2019, as well as by CW1, before and during the Class Period, Teligent had a widespread failure to implement required procedures and controls, exacerbated by a badly understaffed Quality Control department. This resulted in Teligent systematically failing to comply with FDA regulations, which undermined the integrity of the data Teligent submitted to the FDA in support of its ANDAs. Indeed, Teligent not only had to redo tests and studies for the faulty ANDAs it had submitted, so that they had a chance of receiving approval, but it had to implement a host of new procedures and controls across its laboratory and related infrastructure – in response to compliance failures the FDA had specifically identified and the many others Teligent was now expressly warned to correct – to improve the quality of future ANDA submissions and rebuild its standing with the FDA. This delayed the potential approval of Teligent's already submitted ANDAs, caused the submission of its new ANDAs to slow to an almost complete halt, made the strategy of expanding into new business lines impossible to implement, and resulted in a waste of Teligent's high R&D and other expenses, which the dwindling pipeline could not earn sufficient revenue to cover.

(b) Moreover, they concealed the September 2016 483 Letter, accompanying EIR, and subsequent follow-up letter from the FDA, which contained observations of

multiple, systematic compliance failures in Teligent's procedures and laboratory controls and undermined the integrity of the data that Teligent was submitting in support of its ANDAs. They concealed that information notwithstanding that their own (undisclosed) follow-up letter to the FDA in October 2016 stated that "***Teligent takes these observations extremely seriously***." [Emphasis added]. As set forth herein, responding to those observations and warnings required a substantial amount of Teligent's already overtaxed resources, both for the ANDAs already submitted and prospective infrastructure fixes, thereby delaying the approval of existing ANDAs, delaying the submission of new ANDAs, and limiting Teligent's ability to execute its business plan. This further showed that Teligent was already experiencing serious regulatory problems with its core products, and was not prepared or positioned to expand into new business lines.

(c) Also, they concealed that the injectable facility was already experiencing significant delays in its development timeline, making it unlikely to support injectable products on the timeline Defendants promised. Moreover, amidst the development failures set forth in the preceding paragraphs, Teligent was already experiencing a substantial slowdown in its ANDA submissions for its core topical business, which, in turn, delayed and threatened its ability to develop and produce the more complex injectable drugs on the promised timeline.

VII. NO SAFE HARBOR

176. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the statements alleged to be false or misleading herein that relate to then-existing facts and conditions, nor does it apply to any material omissions alleged herein. To the extent that statements alleged to be false or misleading are characterized as forward-looking, the statutory safe harbor does not apply to such statements because they were not

sufficiently identified as "forward-looking statements" when made, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statements, and Defendants had actual knowledge that the forward-looking statements were materially false or misleading at the time each such statement was made.

VIII. COUNTS

FIRST COUNT
Violation of §10(b) of the Exchange Act and
Rule 10b-5 Promulgated Thereunder Against All Defendants

177. Plaintiff repeats and realleges each and every allegation set forth above as if fully set forth herein. This claim is asserted against all Defendants.

178. During the Class Period, Defendants: (i) knowingly, or with reckless disregard, deceived the investing public, including Plaintiff and Class members, as alleged herein; (ii) artificially inflated and/or maintained the market price of Teligent common stock; and (iii) caused Plaintiff and Class members to purchase, or otherwise acquire, Teligent common stock at artificially inflated prices.

179. Each of the Defendants, in violation of §10(b) of the Exchange Act and Rule 10b-5(b), made false statements of material facts and omitted to state material facts necessary to make the statements made by Defendants not misleading, which operated as a fraud and deceit upon Plaintiff and the Class, in an effort to create or maintain an artificially inflated price of Teligent common stock during the Class Period. Defendants' material misrepresentations and omissions are alleged in §IV, *supra*.

180. As a result of their making and/or substantially participating in the creation of affirmative statements to the investing public, Defendants had a duty to promptly disseminate

truthful information that would be material to investors in compliance with applicable laws and regulations.

181. As an officer, director, and controlling person of a publicly held Company, whose common stock is registered with the SEC, pursuant to the Exchange Act, traded on the Nasdaq, and governed by the provisions of the federal securities laws, Grenfell-Gardner had a duty to promptly disseminate accurate and truthful information regarding the Company's financial condition and performance, growth, operations, financial statements, business, markets, management, earnings, and present and future business prospects, and to correct any previously issued statements that had become materially false or misleading, so that the market price of the Company's publicly traded securities would be based upon truthful and accurate information.

182. Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails, made, or substantially participated in, the creation and/or dissemination of false or misleading statements of material fact, as set forth herein, or with reckless disregard failed to ascertain and disclose truthful facts, even though such facts were available to them.

183. The facts alleged herein give rise to a strong inference that each of the Defendants acted with scienter. Each of the Defendants knew, or recklessly disregarded, that the Class Period statements set forth in §IV, *supra*, contained material misrepresentations and omissions for the reasons set forth herein.

184. By virtue of Grenfell-Gardner's position of management and control within Teligent, he had access to undisclosed adverse information about the Company, its business, operations, operational trends, finances, and present and future business prospects. Grenfell-Gardner would ascertain such information through the Company's internal corporate documents;

conversations and connections with corporate officers and employees; attendance at sales, management, and Board of Directors meetings, including committees thereof; and reports and other information provided to him in connection with his roles and duties as Teligent officer and director, including from the FDA.

185. Grenfell-Gardner was aware of, or recklessly disregarded, that material misrepresentations and omissions were being made regarding the Company, and approved or ratified such statements in violation of the federal securities laws.

186. As a result of Defendants' dissemination of the materially false or misleading information, and their failure to disclose material facts, as alleged herein, the market price of Teligent common stock was artificially inflated throughout the Class Period. Unaware that the market price of Teligent common stock was artificially inflated; relying directly or indirectly on the false or misleading statements made by Defendants, at the times such statements were made, or relying upon the integrity of the markets in which Teligent common stock traded; and in the absence of material adverse information that was known, or recklessly disregarded, by Defendants, but not disclosed to the public, Plaintiff and Class members purchased or otherwise acquired Teligent common stock at artificially inflated prices.

187. Had Plaintiff and the other Class members known the truth regarding the problems that Teligent was experiencing, which was not disclosed by Defendants, Plaintiff and other Class members would not have purchased, or otherwise acquired, Teligent common stock, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

188. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other Class members suffered damages in connection with their respective purchases and sales of

Teligent common stock during the Class Period, when the artificial inflation in the price of such securities dissipated, as the truth regarding Defendants' conduct was revealed, causing the price of Teligent common stock to decline, resulting in economic losses to Plaintiff and the Class.

189. By reason of the foregoing, Defendants violated §10(b) of the Exchange Act and Rule 10b-5(b), promulgated thereunder, and they are liable to Plaintiff and the Class for damages suffered in connection with their transactions in Teligent common stock during the Class Period.

SECOND COUNT
Violation of §20(a) of the Exchange Act
Against Grenfell-Gardner

190. Plaintiff repeats and realleges each and every allegation set forth above as if fully set forth herein. This claim is asserted against Defendant Grenfell-Gardner.

191. Teligent is a primary violator of §10(b) and Rule 10b-5, promulgated thereunder.

192. Grenfell-Gardner acted as controlling persons of Teligent within the meaning of §20(a) of the Exchange Act. Grenfell-Gardner had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence, and during the Class Period, did exercise his power to control and influence, the conduct giving rise to the violations of the federal securities laws alleged herein. Grenfell-Gardner prepared, or was responsible for preparing, the Company's press releases and SEC filings, and made statements to the market in SEC filings, annual reports, press releases, news articles, and conference calls. Grenfell-Gardner controlled Teligent and each of its employees.

193. Grenfell-Gardner was able to, and did, control the content of the various SEC filings, press releases, and other public statements pertaining to the Company during the Class Period. Grenfell-Gardner was provided with copies of the documents, as alleged herein, to contain material misrepresentations and omissions prior to, or shortly after, their issuance and had the ability and/or opportunity to prevent the issuance of such documents or cause them to be corrected.

Accordingly, Grenfell-Gardner is responsible for the accuracy of the Company's public reports and releases.

194. By virtue of his position as a controlling person of Teligent, and by reason of the conduct described in this Count, Grenfell-Gardner is liable pursuant to §20(a) of the Exchange Act for controlling a primary violator of the federal securities laws. As a direct and proximate result of Grenfell-Gardner's wrongful conduct, Plaintiff and other Class members suffered damages in connection with their purchases of the Company's securities during the Class Period.

IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of Plaintiff and all other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

X. JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

DATED: December 9, 2019

SCOTT+SCOTT ATTORNEYS AT LAW LLP

/s/ Max R. Schwartz
Max R. Schwartz
David R. Scott
Thomas L. Laughlin, IV
Donald A. Broggi
Anjali Bhat

Jeffrey P. Jacobson
The Helmsley Building
230 Park Avenue, 17th Floor
New York, NY 10169
Telephone: (212) 223-6444
Facsimile: (212) 223-6334
mschwartz@scott-scott.com
david.scott@scott-scott.com
tlaughlin@scott-scott.com
dbroggi@scott-scott.com
abhat@scott-scott.com
jjacobson@scott-scott.com

Counsel for Plaintiff Oklahoma Police Pension Fund and Retirement System